[*Submitting Counsel on Signature Page*]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: MCKINSEY & CO., INC. NATIONAL PRESCRIPTION OPIATE CONSULTANT LITIGATION This Document Relates to: ALL NAS ACTIONS	CASE NO. 21-MD-02996-CRB (SK) **AMENDED MASTER COMPLAINT (NAS)** **REDACTED** **JURY TRIAL DEMANDED**

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I. INTRODUCTION

1. This is a concerted action case filed on behalf of eleven babies born in eight different states[1] against four Defendants. All four Defendants are affiliated companies under the umbrella of McKinsey & Company, Inc., and collectively referred to as "McKinsey." Each "count" or claim against McKinsey, below, corresponds to an underlying tort committed by one or more of McKinsey's former opioid-manufacturing clients. These underlying torts fall broadly into four categories: negligence and negligence per se; public nuisance; failure to warn; and misrepresentation. McKinsey is liable for these torts because it encouraged or substantially assisted its client or clients in the underlying conduct despite McKinsey's awareness and knowledge at the time that the conduct it was encouraging and assisting required the client to violate at least one clear legal duty. McKinsey is also liable for the underlying torts of its clients because McKinsey conspired with its clients or one or more individuals associated with the client to breach the legal duty.

2. All eleven babies were born with permanent, physical, developmental injuries caused by prenatal exposure to prescription opioid medications consumed by their birth mother, with or without a proper prescription, during her pregnancy. Specifically, the babies were born with one or more of the following injuries: gastroschisis (one baby) or other congenital malformations (two babies); attention deficit disorders (six babies); cognitive impairments, learning disabilities or other developmental and language delays (ten babies); respiratory impairments (six babies); vision impairments (eight babies); and spina bifida or other neural tube defects (one baby).[2]

II. PREAMBLE

3. This Amended Complaint is filed in response to the Court's order dismissing NAS Claimants' Master Complaint with leave to amend. (ECF No. 573.)

4. This Complaint is an administrative device as described in *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D.133, 142 (E.D. La. 2002) for the specific purposes of enabling the Court

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[1] Those eight birth states are: Tennessee, Utah (three babies), Kentucky, Oklahoma, West Virginia (three babies), Colorado, California, and Nevada.

[2] This list of permanent physical injuries is not exhaustive.

to address the threshold issues it articulated in its statements and Orders to date, and does not supersede the complaints filed in the individual actions consolidated in this multi-district litigation for pretrial proceedings only. *See Gelboim v. Bank of Am.*, 574 U.S. 405, 413 n.3 (2015).

5. Plaintiffs Sarah Riley, Brandi Shatnawe, and Katrina Cox, each on behalf of their minor children, have not previously filed actions against the Defendants. These Plaintiffs respectfully request that this Master Complaint be deemed their original complaint under the direct-file provisions of PTO 7.

6. This Amended Master Complaint hereby incorporates by reference all allegations and claims for relief asserted in the original Master Complaint.

III. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action for the reasons stated in each underlying complaint.

8. This Court has personal jurisdiction over McKinsey for the reasons stated in each underlying complaint.

9. Venue is appropriate for pretrial proceedings under *In re McKinsey & Co., Inc., Nat'l Prescription Opiate Consultant Litig.*, MDL No. 2996, 2021 WL 2351628 (J.P.M.L. June 7, 2021).

IV. PARTIES

A. NAS Plaintiffs

10. Plaintiffs are minor children who suffered injuries resulting from their exposure to opioids in the womb, including but not limited to birth defects, cognitive deficits, developmental delays, and physical symptoms associated with what is commonly referred to as "NAS" (collectively, "Minor Plaintiffs") and their legal guardians.

11. Katrina Cox, on behalf of her natural minor child, K.A., all residents of Memphis, Tennessee. Upon information and belief, Ms. Cox's opioid prescriptions were prescribed and filled in Tennessee. Absent direct filing, Plaintiffs would have filed in the Western District of Tennessee.

12. Sarah Riley, on behalf of her natural minor child, E.A.B, all residents of Layton, Utah. Upon information and belief, Ms. Riley's opioid prescriptions were prescribed and filled in Utah, where E.A.B. was born. Absent direct filing, Plaintiffs would have filed in the District of Utah.

13. Brandi Shatnawe, on behalf of her natural minor child, A.A., all residents of Edmond, Oklahoma. Upon information and belief, Ms. Shatnawe's opioid prescriptions were prescribed and filled in Oklahoma, where A.A. was born. Absent direct filing, Plaintiffs would have filed in the Western District of Oklahoma.

14. Hayden Travis Blankenship, on behalf of his natural minor child, Z.D.B.B., both residents of Peterstown, West Virginia. Upon information and belief, Z.D.B.B.'s biological mother's opioid prescriptions were prescribed and filled in West Virginia, where Z.D.B.B. was born. Absent direct filing, Plaintiffs would have filed in the Southern District of West Virginia.

15. Marina Brizendine on behalf of her natural minor child, S.B., both currently residents of Chandler, Texas. At all relevant times, Ms. Brizendine and S.B. lived in Kentucky. Ms. Brizendine's opioid prescriptions were prescribed and filled in Kentucky, where S.B. was born. Absent direct filing, Plaintiffs would have filed in the Western District of Kentucky.

16. April Hudak, on behalf of her natural minor child, H.S., both residents of Golden, Colorado. Ms. Hudak's opioid prescriptions were prescribed and filled in Colorado, where H.S. was born. Absent direct filing, Plaintiffs would have filed in the District of Colorado.

17. Timothy Lambert, on behalf of his natural minor child, M.L., all residents of Beckley, West Virginia. Upon information and belief, M.L.'s biological mother's opioid prescriptions were prescribed and filled in West Virginia, where M.L. was born. Absent direct filing, Plaintiffs would have filed in the Southern District of West Virginia.

18. Jacqueline Ramirez on behalf of her natural minor child, R.R., both residents of Oxnard, California. Ms. Ramirez's opioid prescriptions were prescribed and filled in California, where R.R. was born. Absent direct filing, Plaintiffs would have filed in the Central District of California.

19. Julieann Valdez on behalf of her natural minor children, J.V. and M.V, all residents of Las Vegas, Nevada. Ms. Valdez's opioid prescriptions were prescribed and filled in Utah, where J.V. was born. By the time Ms. Valdez moved to Nevada, where M.V. was born, she was already dependent on opioids. Under the proposed direct-filing provision, Plaintiffs indicate they would have filed in the Southern District of New York.

20. Cynthia Woolwine, on behalf of her natural minor child, E.G.W., all residents of Oceana, West Virginia. On information and belief, Ms. Woolwine's opioid prescriptions were prescribed and filled in West Virginia, where E.G.W. was born. Absent direct filing, Plaintiffs would have filed in the Southern District of West Virginia.

B. <u>Defendants</u>

21. Defendant McKinsey & Company, Inc. is a corporation organized under the laws of the state of New York. McKinsey's principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, at 80 State Street, Albany, NY 12207.

22. Defendant McKinsey Holdings, Inc. is a Delaware corporation with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

23. Defendant McKinsey & Company, Inc. United States is a Delaware corporation with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

24. Defendant McKinsey & Company, Inc. Washington D.C. is a Delaware corporation with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

25. Upon information and belief, McKinsey & Company, Inc. is the parent company of McKinsey & Company Holdings, Inc., which is itself the parent company of both McKinsey &

Company, Inc. United States and McKinsey & Company, Inc. Washington D.C. Upon information and belief, each subsidiary corporation is wholly owned by its parent. Despite the corporate form, McKinsey began as a partnership and still refers to its senior employees as "partners." Those partners are the firm's shareholders. Collectively, these four Defendants are referenced throughout as "McKinsey."

26. McKinsey a is global management consultancy with offices in over 130 cities in 65 countries, including the following United States cities: Atlanta, GA; Austin, TX; Houston, TX; Dallas, TX; San Francisco, CA; Los Angeles, CA; Redwood City, CA; Boston, MA; Charlotte, NC; Chicago, IL; Cleveland, OH; Denver, CO; Detroit, MI; Miami, FL; Miramar, FL; Tampa, FL; Minneapolis, MN; Summit, NJ; New York, NY; Philadelphia, PA; Pittsburgh, PA; Seattle, WA; St. Louis, MO; Stamford, CT; Waltham, MA; and Washington, D.C.

27. McKinsey is registered to do business in all fifty states.

V. NATURE OF THE CASE AND LEGAL THEORIES

28. The instant case is different than the typical civil action or products liability case. McKinsey did not make or sell opioids. McKinsey "consulted" with many who did. Plaintiffs allege that, in the course of many specific consulting arrangements—described in detail in the "Factual Allegations and Specific Client Engagements" section below—McKinsey *encouraged* its opioid-manufacturing clients to breach their statutory and common-law duties. In other words, McKinsey *knew* that the course of conduct McKinsey was recommending to its clients constituted a breach of duty—in many cases, the conduct constituted an outright violation of statutory and criminal laws—and encouraged its clients to engage in that unlawful conduct anyway. McKinsey's conduct is actionable for that reason. McKinsey's and McKinsey's clients' actionable and unlawful conduct falls into two broad categories, described in turn.

A. Illegal Promotion and Sale of Opioids to Prescribers Whose Patients Were Known Abusers and Diverters

29. McKinsey encouraged and provided substantial assistance to many of its opioid-manufacturing clients to promote their products and to sell them to prescribers whose patients were known—to the manufacturers and certainly to McKinsey—to be abusing and diverting

opioids.[3] In all or at least most of these same instances, McKinsey partners and associates also conspired with the client company or with one or more persons associated with the client company (for example, certain shareholders or board members) to promote and to sell the company's products illegally. In some cases, McKinsey even conspired with certain client insiders to overcome the internal resistance from other client insiders to the illegal scheme.

30. By promoting and selling their controlled substances to prescribers whose patients were known abusers and diverters, McKinsey's clients breached at least two distinct legal duties to the public and to end users of their products. First, it is illegal under the Controlled Substance Act, 21 U.S.C. § 801 et seq., for manufacturers of controlled substances to promote or knowingly sell their products for anything other than legitimate medical purposes.[4] Under the common law of every state, manufacturers also have a duty to exercise reasonable care to avoid foreseeable harm from the use of their products—a duty that requires, at minimum, compliance with all applicable statutes and regulations governing their conduct to avoid foreseeable harm under the legal doctrine of negligence *per se* and related doctrines that vary only slightly, if at all, from state to state.[5] Thus, by promoting and selling their controlled substances to prescribers whose patients were known abusers and diverters, McKinsey's clients breached their duties of reasonable care and were therefore *negligent* or *negligent per se*.

31. Second, manufacturers in most states have a duty not to interfere with the right of the general public to use and enjoy public spaces without fear for their safety, health, or well-being, and especially a duty not to interfere with such public rights through conduct proscribed by statute or regulation.[6] By knowingly promoting and selling drugs to prescribers whose patients

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[3] Specific instances of McKinsey's encouragement of this conduct with specific manufacturers are described in detail in the next section, "Factual Allegations and Specific Client Engagements."

[4] Most states, including West Virginia, have their own laws prohibiting the promotion and sale of controlled substances for other than legitimate medical purposes. *See, e.g.*, W. Va. Code § 60A-1-101, et seq. Under federal law and the laws of most states, manufacturers have a duty to report suspicious conduct by downstream distributors, dispensers, and prescribers to state or federal authorities. *See* 21 U.S.C. § 832.

[5] *See, e.g.*, syl. pt. 1, *Miller v. Warren*, 390 S.E.2d 207 (W. Va. 1990) (holding that the failure to comply with a statute or regulation is *prima facie* negligence); *id.* at 209 ("It is settled law that a statute or regulation . . . sets a floor of due care.").

[6] *See, e.g.*, *Ileto v. Glock Inc.*, 349 F.3d 1191, 1211-12 (9th Cir. 2003) (recognizing right of individuals with special injuries to bring claims against manufacturers for interference with public rights associated with the creation of an illegal secondary gun market); *see generally* Rest. 2d Torts § 821B (explaining that a "public nuisance is an

were known abusers and diverters, in violation of federal and state laws, McKinsey's clients knowingly created, fostered, and sustained an illegal secondary market for opioids, which caused not only increases in the risks and dangers associated with opioid addiction, but also interfered with the public right to the use and enjoyment of public spaces through the resulting, predictable increases in physical danger, likelihood of harassment, risk of theft, fear, filth, disease, and blight in public spaces that predictably result from a robust illegal secondary market for opioids. Thus, by promoting and selling their controlled substances to prescribers whose patients were known abusers and diverters, McKinsey's clients breached their duty to the public and to those, such as Plaintiffs, who suffered special harm from the significant and unreasonable interference with the public right to be free from the deleterious effects of an illegal secondary market for opioids.[7] In short, they committed the tort commonly known as "public nuisance."

32. By knowingly encouraging, providing substantial assistance to, and conspiring with manufacturers to breach (at least) these two distinct legal duties, McKinsey is also liable for the harm that resulted, including the harm to Plaintiffs, under two distinct theories of concerted action liability. First, McKinsey is liable under the theory that Plaintiffs refer to as "aiding and abetting" liability. "For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he …(b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself." *Rest. 2d Torts* § 876(b).[8]

33. Second, McKinsey is also liable under the civil conspiracy doctrine. As one court explained, "A civil conspiracy . . . is . . . a legal doctrine under which liability for a tort may be imposed on people who did not actually commit a tort themselves but who shared a common plan for its commission with the actual perpetrator(s)."[9]

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unreasonable interference with a right common to the general public" and that factors for determining whether an interference is unreasonable include whether "the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience," whether "the conduct is proscribed by a statute, ordinance or administrative regulation," and whether the conduct has produced a "long-lasting effect").

[7] *See* Rest. 2d Torts § 821C(1).

[8] Cited with approval in *Courtney v. Courtney*, 413 S.E.2d 418, 420 (W. Va. 1991); *Price v. Halstead*, 177 W. Va. 592, 597, 355 S.E.2d 380, 386 (1987).

[9] Syl. pt. 8, *Dunn v. Rockwell*, 225 W. Va. 43, 689 S.E.2d 255 (2009).

B. Unlawful Practices Involving the Concealment of Risks and the Inflation of Benefits of Opioids

34. McKinsey encouraged its opioid-manufacturing clients to conceal adverse incidents and other evidence of the risks of their opioids from the public—end users, regulators, researchers, and prescribers. McKinsey also encouraged its opioid-manufacturing clients to overstate or inflate the benefits of their opioids in sales and other presentations and in study summaries and other writings, presentations, and communications intended for prescribers, researchers, and regulators. Beyond encouragement, McKinsey also provided substantial assistance to its clients in the concealment of risks and the inflation of benefits. In many of these same instances, McKinsey partners and associates also conspired with the client company or with one or more persons associated with the client company (for example, certain shareholders or board members) to conceal the risks and inflate the benefits of their opioids in their written and oral communications with researchers, regulators, and prescribers.

35. By concealing the risks and inflating the benefits of their products in their sales, marketing, research, and regulatory communications, McKinsey's clients breached at least two distinct legal duties to end users of their products. The first is the common-law duty that all manufacturers have in all states—whether under the doctrine of strict products liability or negligence—to provide appropriate warnings and instructions for use, in order to minimize the risks of foreseeable harm from their products. Thus, by concealing the risks of their products, manufacturers breached their duties to disclose all known risks of their products, and committed the tort commonly referred to as "failure to warn."

36. The second duty breached by McKinsey's clients is the duty that all manufacturers have in all states not to misrepresent the risks and benefits of their products. By misrepresenting and inflating the benefits of their opioid products, McKinsey's clients committed the tort of intentional or negligent misrepresentation.

37. By knowingly encouraging, providing substantial assistance to, and conspiring with manufacturers to breach these two legal duties, McKinsey is also liable for the harm that

resulted, including the harm to Plaintiffs, under the same two theories of concerted action liability described in the previous section: for "aiding and abetting"[10] and civil conspiracy.[11]

C. Concerted Action Liability Requires Actual Knowledge on the Part of the Abettor or Co-Conspirator That the Conduct of the Other Constitutes a Breach of the Other's Legal Duty

38. The purpose of this section is to put the reader's mind at ease by identifying and acknowledging a critical distinction between the potential tort liability of a third party, such as McKinsey, under the aiding and abetting and conspiracy doctrines, on the one hand, and the liability of the underlying tortious actor, such as McKinsey's client manufacturers, on the other. McKinsey's client manufacturers have a duty to know those things that are knowable about their products when promoting, marketing, selling, and communicating with others about them. McKinsey's clients, for example, may have a duty to know (or to figure out) which prescribers are prescribing opioids to patients who are diverting or abusing them, and McKinsey's clients definitely have a duty to know the risks and benefits of their products, at least to the extent the true risks and benefits are knowable. Thus, the phrase "knew or should have known" is commonplace in any discussion about manufacturer liability, whether under strict products liability or negligence.

39. McKinsey, however, does not have that same duty. In order for McKinsey to be liable for any breach of a duty by a client, McKinsey not only has to encourage, provide substantial assistance to, or conspire with its client to breach that duty, but also McKinsey has to have actual *knowledge*—not mere "constructive knowledge" or "should have known"-type notice—that the conduct it encouraged, assisted, or conspired with the other to engage in constituted a breach of the other's duty or duties.[12] In the next section, we demonstrate, through detailed factual allegations, that McKinsey encouraged, assisted, and conspired with its clients to

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[10] *Rest. 2d Torts* § 876(b) ("For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he . . . . (b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself.").

[11] Syl. pt. 8, *Dunn v. Rockwell* 689 S.E.2d 255 (W. Va. 2009) ("A civil conspiracy . . . is . . . a legal doctrine under which liability for a tort may be imposed on people who did not actually commit a tort themselves but who shared a common plan for its commission with the actual perpetrator(s).").

[12] *See Rest. 2d Torts* § 876(b) ("For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he . . . knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself.").

breach their legal duties—knowing that the conduct it encouraged involved breaching its clients' legal duties.

VI. ALLEGATIONS RELATED TO SPECIFIC CLIENT ENGAGEMENTS

A. Client Engagement No. 1: McKinsey Encourages Janssen to Target Prescribers with Abuse- and Diversion-Prone Patients

40. While most of the scrutiny of McKinsey's role in the Opioid Crisis has centered on its work on behalf of Purdue, the first record of McKinsey's opioid related work relates to J&J's fentanyl patch, not McKinsey's work to promote Purdue's OxyContin. That record is a scheduling note from 1998 for McKinsey partner Arnab Ghatak with a one word description- "Duragesic."

41. Fentanyl was first synthesized by Paul Janssen and his pharmaceutical company Janssen Pharmaceuticals in 1959. In the 1990s, the company (by then owned by Johnson & Johnson) developed Duragesic, which is a transdermal patch that administers fentanyl to the patient wearing it. Duragesic proved to be one of the most successful analgesic pharmaceutical products ever developed, with sales in 2004 (its last year of patent life) exceeding $2.4 billion. The success of the fentanyl patch caused many generic companies to produce equivalents once it went off patent.

42. McKinsey was an integral part of fentanyl's success. As early as 2002, McKinsey encouraged Janssen to pursue unlawful methods to boost sales of its opioids. For example, on March 14, 2002, McKinsey prepared a confidential report for Johnson & Johnson's subsidiary Janssen regarding how to market their opioid Duragesic. One of the recommendations McKinsey provided to Johnson & Johnson was that they concentrate their sales and marketing efforts on doctors that were already prescribing large amounts of other opioids.

43. McKinsey also helped Janssen target its opioid marketing by identifying "priority growth opportunities" and growth strategies for Duragesic, which in practice meant focusing on markets rife with potential for abuse and diversion. McKinsey rhetorically asked, for example, "What are settings of care for opioid high-prescribers and treaters of back pain?"

44. Specifically, McKinsey encouraged Janssen to target "high abuse-risk patients (e.g., males under 40)." This targeting allegedly would take advantage of the marketing claim that Duragesic "was harder to abuse than other opioids on the market." In reality, as McKinsey knew, targeting abuse-prone young men would help to foster an illegal secondary market for opioids, which, McKinsey knew, would benefit all of its opioid manufacturing clients.

B. Client Engagement No. 2: McKinsey Encourages Purdue Pharma to Recapture Sales Lost As a Result of Efforts to Combat OxyContin Abuse and Diversion

1. Background

45. The story of Purdue Pharma's role in the initial explosion of opioid prescriptions in the late 1990s and early 2000s is well-known at this point. For example, we know from government documents resulting in a Purdue guilty plea in 2007 that, beginning in 1996 and continuing until at least 2007, Purdue falsely marketed OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause withdrawal than physicians were trained to believe based on years of the medical community's experience with all opioids. During this time period, Purdue trained its sales staff to tell physicians that the risk of addiction with opioids like OxyContin was "less than one percent," even though the only (scant) data it possessed were from reported rates of opioid addiction in acute pain settings, not the long-term treatment of chronic pain that its sales staff was pushing on physicians, including primary care physicians, with the "less than one percent" message.

46. It is somewhat less well-known that Purdue's OxyContin (usually upwards) sales trajectory included several dips and flatlines, before and after 2007, caused by external efforts to curb or curtail what came to be known as the "opioid epidemic" – the widespread diversion and abuse of prescription opioids in the United States. Those dips in Purdue's sales – and the options that Purdue contemplated in response to the dips, as well as the actions in response that Purdue (and others) ultimately chose – provide the clearest window we have into what Purdue and McKinsey knew about Purdue's ultimate customer base, and how to reach it.

47. Purdue's first major setback occurred more than five years before the 2007 guilty plea, when, in 2001, the DEA released a communication to the pharmaceutical industry called,

"Action Plan to Prevent the Diversion and Abuse of OxyContin." The DEA's 2001 OxyContin Action plan specifically flagged the abuse and diversion potential of extended-release formulations of oxycodone. Data published by the CDC in 2012 show that the overall industry response, including opioid prescribers, was simply to switch a large swath of patients from extended-release formulations to immediate-release formulations of oxycodone. Over the next five years, total prescriptions for extended-release formulations of oxycodone like OxyContin remained relatively flat. However, there was no interruption in the overall upward trend of oxycodone prescriptions. Over those same five years, from 2001 to 2006, prescriptions for immediate-release formulations of oxycodone rose by 56%.

48. Purdue's second major setback occurred in 2007, when a Purdue affiliate pled guilty to misbranding OxyContin. Purdue agreed to pay more than $600 million in penalties as part of that plea agreement, and Purdue entered into a "Corporate Integrity Agreement" with the United States Department of Health and Human Services.

49. Partially in response to these setbacks, and partially motivated by concern about the impending expiration of its patent on the original OxyContin formulation, Purdue developed a so-called "abuse deterrent formulation" of OxyContin ("ADF OxyContin"). Purdue claims, with some evidence, that ADF OxyContin is more difficult to crush to a powder form or dissolve in liquid, and thus more difficult to abuse by snorting or injecting the substance. Purdue received regulatory approval to begin marketing ADF OxyContin in April 2010. In August 2010, Purdue discontinued the original formulation of OxyContin and thereafter marketed and sold only ADF OxyContin.

2. Declining Sales by Total Milligram After August 2010

50. It is undisputed that sales of OxyContin began to decline significantly following the introduction of ADF OxyContin, particularly on a total milligram basis. In June 2011, less than one year after completing the transition to ADF OxyContin, internal Purdue documents show that executives expected a budget shortfall for the year of $1 billion, based on a revised forecast

of revenues from OxyContin sales from $3.9 billion to $2.8 billion.[13] The decline was most pronounced in the higher dose tablets of OxyContin, which are preferred by abusers and diverters.[14]

51. The declining sales trend continued into 2013. According to a McKinsey presentation to high-ranking Purdue executives in July 2013, total milligrams of OxyContin sold declined by 7.2% in 2012, and by another 8.7% in the first quarter of 2013 compared to the first quarter of 2012.

52. Purdue's own researchers largely attributed the post-ADF decline in sales to a decline in prescriptions written for "patients" who had been abusing or diverting OxyContin. For example, a study initially presented to Purdue's board in October 2011 looked at prescription patterns over a two-year period spanning the year before and the year after the introduction of ADF OxyContin. Purdue's researchers found that OxyContin prescriptions by so-called "Region Zero" providers—providers flagged by Purdue's legal department as suspected diverters and not to be called upon by Purdue sales representatives[15]—declined by 86%, a decline that significantly outpaced the decline in prescriptions written by other prescribers. The decline was even more pronounced among Region Zero prescribers for the higher milligram tablets, which is significant because OxyContin abusers and diverters tend to prefer higher milligram tablets.[16]

53. Later assessments conducted by Purdue researchers purport to show that the decline in OxyContin abuse, based on reports of OxyContin abuse in publicly available databases from 2011 to 2013, outpaced the decline in OxyContin prescriptions following the introduction of ADF OxyContin.[17] Purdue's scientists and researchers concluded that ADF OxyContin was

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[13] Honig, Rachael, et al., Letter Memorializing Plea Agreement with Purdue (October 20, 2020), "Addendum A to Settlement Agreement" at 12 ¶¶ 59–60.

[14] *Id.*

[15] The basis for Purdue's legal department's "Region Zero" determinations are not transparent. While, theoretically at least, those determinations could take into account reports of suspicious activity from Purdue's own sales representatives, it appears that in practice the list was compiled by the legal department based on reports from government agencies or reports of law enforcement investigations or interventions.

[16] Honig, Rachael, et al., Letter Memorializing Plea Agreement with Purdue (October 20, 2020), "Addendum A to Settlement Agreement" at 15 ¶ 76.

[17] Coplan, P. & Chilcoat, H., "Effects of Reformulating OxyContin on Opioid Abuse in 6 National US Abuse Surveillance Systems," Presentation at the International Society for Pharmacoepidemiology Annual Meeting (August 2015).

actually working—that is, it was having its intended effect of deterring abuse, with the unintended (but unavoidable) effect that Purdue was losing a significant portion of the segment of its sales from prescriptions that went to abusers and diverters. In other words, Purdue's researchers believed that the drop in OxyContin sales following the introduction of ADF OxyContin should be attributed directly to a reduction in abuse and diversion of OxyContin, meaning that the lost sales had been going mostly to patients using the drug for some illegal purpose—that is, something other than a legitimate medical purpose.

54. McKinsey's own internal documents and emails indicate that [redacted]

55. However, key members of the Sackler family—Purdue's main shareholders and controlling board members—had very different ideas about the inevitability or acceptability of the loss of OxyContin sales revenues and attendant profits. Richard Sackler and Mortimer Sackler fretted throughout 2012 and 2013 about the loss of OxyContin sales over the prior two years and queried Purdue's management about what they planned to do about it.[20] At one point, Mortimer

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[18] For example, [redacted] MCK-MDL2996-0079538.

[19] For example, [redacted] MCK-MDL2996-0364607.

[20] Honig, Rachael, et al., Letter Memorializing Plea Agreement with Purdue (October 20, 2020), "Addendum A to Settlement Agreement" at 12–13 ¶¶ 62 & 65.

Sackler emailed other board members and suggested they consider replacing both Purdue's CEO and head of sales.[21] Upon information and belief, in June or July 2013, the Sacklers turned to their old friends at McKinsey to help them convince the board to go after and try to recapture the sales and profits Purdue had lost following the switch to the new formulation—former OxyContin sales that Purdue's own researchers and most executives attributed to illegal prescriptions and purchases for non-medical uses.

3. <u>Enter McKinsey</u>

56. [redacted].[22]

57. [redacted]

58. There are two important takeaways from this internal Purdue/McKinsey debate about the cause of the declining OxyContin sales in the three years before McKinsey's summer 2013 engagement and analysis. [redacted]

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[21] *Id.* at 13 ¶ 63.

[22] *See, e.g.*, [redacted], MCK-MDL2996-0022535–73; [redacted] MCK- MDL2996-0022916–37 [redacted] MCK MDL2996-0079144–50.

[redacted]

59. [redacted]

60. Internal McKinsey emails reveal that [redacted].[23]

[23] For example, [redacted] MCK-MDL2996-0079539.

61. Similarly, McKinsey was not interested in—nor hired by the Sacklers for the purpose of—considering a full range of possible sales approaches available to Purdue, [redacted].[24] McKinsey knew the solution to Purdue's problem before it started the analysis.

62. [redacted] The solution, according to McKinsey, was to use higher-level contacts (at McKinsey and Purdue) to apply pressure on the distributors and larger pharmacies (e.g., Walgreens) to resume stocking and dispensing OxyContin at higher milligrams and higher rates, and to direct Purdue's sales force to focus single-mindedly on selling OxyContin to high-volume prescribers.

63. McKinsey even suggested—somewhat comically given that it had already identified public and government pressures to curtail and more closely monitor distribution and sales of opioids and the corresponding reluctance, identified by McKinsey, on the part of distributors and pharmacies to sell them anyway—that Purdue explore or at least threaten to explore direct-to-consumer distribution methods that would bypass obstinate distributors and pharmacies. McKinsey informed Purdue that some of its other pharmaceutical clients—makers and sellers of non-scheduled drugs—were exploring such direct-to-consumer channels and could serve as models for a Purdue program.

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[24] For example, [redacted] MCK-MDL2996-0079538.

[25] *See, e.g.*, [redacted] MCK-MDL2996-0022535–73; [redacted], MCK- MDL2996-0022916–37 [redacted] MCK MDL2996-0079144–50.

64. Upon information and belief, McKinsey was actually signaling to Purdue's higher-level executives and board members—and probably informed them in oral communications—that, through the strength of its relationships with other pharmaceutical clients, McKinsey could bring considerable pressure to bear on stubborn distributors and pharmacies by threatening to cut them out of the pharmaceutical distribution model altogether, and not just out of sales of Purdue's problematic pills, which were already a headache for them. Upon information and belief, McKinsey did in fact use back channels to threaten stubborn distributors and pharmacies to resume stocking, distributing, and dispensing OxyContin or else face the prospect of its clients—and not just Purdue—devoting more and more resources to direct-to-consumer sales efforts, which would effectively destroy their businesses. This, upon information and belief, suggests a McKinsey-variation of the old-school approach to promoting an illegal racket: "Hey, that's a nice little business you have there. It would be a shame if something happened to it."

65. In any event, McKinsey's recommended back-channel, high-level pressure on distributors and pharmacies worked, and shortly after August 2013, distributors and pharmacies relaxed their policies on distributing and dispensing OxyContin and other opioids.

66. McKinsey was not stupid in the way it presented its plan for re-directing Purdue's sales force to the high-volume prescribers whose patients abuse and divert drugs. Its primary recommendation was the bluntest of blunt hammers—to double or more than double the number of sales calls to the very highest volume prescribers of OxyContin, while pulling sales resources off of lower-volume prescribers and other drugs in Purdue's portfolio. This primary initiative had to be dressed up in consultant-speak and re-styled as just one important part of an elaborate but obscure and proprietary sales-targeting formula, for two reasons: First, it was patently illegal, given that McKinsey knew that the decline in prescriptions by those high-volume prescribers was due primarily if not exclusively to a reduction in prescriptions to abusers and diverters (i.e., non-medical users) and what it was advocating was pressuring them to resume those prescriptions, but also too obvious and easy to justify McKinsey's exorbitant time and fees.

67. McKinsey came up with a name for its recommended sales approach, and started referring in presentations to replacing Purdue's "decile-based" physician targeting approach with

a "workload-based" physician-targeting scheme. We can only speculate as to why the new approach was branded as "workload-based" or whose "workload" the term refers to—the sales reps, the targeted physicians, the DEA's, or maybe someone else's. McKinsey catchphrases appear to be selected not because they capture the essence of the recommendation, but because they obscure the painfully obvious nature of it. Whatever the name's origin or meaning, in practice it boiled down to doubling or in some cases more than doubling the number of sales calls to prescribers whose patients were suspected diverters and abusers of opioids at the expense of sales calls to low-volume prescribers of OxyContin and other Purdue drugs being prescribed for legitimate medical purposes.[26]

68. As for the rest, the short version is that McKinsey's encouragement and supporting presentations—which, however repetitive, simplistic, clumsy, and susceptible to many different interpretations they may be on close inspection, in a slideshow presentation created the impression of Serious Analysis—were instrumental in aiding the Sacklers in their efforts to bully and browbeat Purdue's management out of its legitimate concerns about the riskiness of a marketing and sales strategy focused on reopening the lost channels and heavily lubricating the remaining channels of known OxyContin abuse and diversion. As a result of Purdue's and McKinsey's higher-level pushback on distributors and dispensers and its "workload-based" program of dramatically increased sales calls to high-volume prescribers, coupled with McKinsey-inspired sales-pitch pressure on prescribers to prescribe higher-dose pills, the momentum shifted, and abuse and diversion of OxyContin and other opioids started soaring again in late 2013 and for years thereafter.

[26] Here is a more complete summary of McKinsey's encouragement and advice to Purdue, in language that more closely resembles the language McKinsey itself used: [redacted]

4. McKinsey Knew Exactly What It Was Encouraging

69. Returning to the original debate regarding the explanation for the decline in OxyContin sales, especially on a total milligram basis, between the Purdue executives and the McKinsey/Sackler side, what is important is that both sides explained the decline by efforts aimed at reducing abuse and diversion. This means that McKinsey *knew* that trying to recapture the lost OxyContin sales was an effort to recapture sales that had been going to diverters and abusers—sales that are illegal and expose anyone involved in the sale who knows the illegal purpose (and probably even those who only suspect an illegal purpose) to criminal liability. In other words, McKinsey *knew* that, by recommending ways for Purdue to recapture that lost OxyContin revenue, it was encouraging Purdue to violate the law and to actively market OxyContin for sale ultimately to end users who intended to abuse and divert OxyContin.

70. In fact, McKinsey's entire pitch to Purdue's executives—that the revenue decline is due to downstream impediments to OxyContin access, not reduced end-user demand for the ADF formulation—is a thinly coded way of saying: "Don't worry. Abusers and diverters still want the ADF version of the pill, especially in high doses, but our downstream sellers are restricting access and making it harder for them to get those high doses they crave. We need to work to lift those impediments, not switch to selling other, less lucrative products."

C. Client Engagement No. 3: McKinsey Encourages Purdue to Falsely Claim That There Is Insufficient Evidence of OxyContin-Related Birth Defects

71. McKinsey drafted, edited, directed, and oversaw Purdue's blatant misrepresentations to the FDA and health care providers related to the link between congenital malformations and in utero opioid exposure.

72. Since the earliest known engagements with Purdue in 2004, McKinsey insinuated itself into the inner workings of Purdue's mandatory pharmacovigilance reporting to the FDA. One part of the pharmacovigilance reporting is issuance of Periodic Safety Update Reports (PSURs) to address new studies and articles that discuss the efficacy and safety of pharmaceuticals.

73. Upon information and belief, in 2013 and again in 2017, McKinsey directed and oversaw Purdue's issuance of PSURs related to scientific articles that associated "early pregnancy maternal analgesic treatment and certain birth defects."

74. Both the 2013 and the 2017 PSURs dealt with the findings of the National Birth Defect Prevention Study to the 14th Annual Maternal and Child Health Epidemiology Conference. "In the study 17,449 cases of the outcomes of pregnancies where there was maternal opioid exposure were compared with 6,701 controls. Therapeutic opioid use was statistically significantly associated in infant offspring conoventricular septal defects, atrioventricular septal defects, hypoplastic left heart syndrome, spina bifida and gastroschisis."

75. Upon information and belief, McKinsey encouraged Purdue to lie in its 2013 PSUR and claim that "there was insufficient evidence to support a causal relationship between oxycodone hydrochloride therapy and the occurrence of congenital anomalies."

76. Upon information and belief, McKinsey encouraged Purdue to lie in its 2017 PSUR and claim that "[t]here is insufficient evidence for a causal relationship, and in general the estimated increase in risk appears to lie within the range reported by similar studies."

77. Separate and apart from the studies mentioned in the PSURs, McKinsey was also privy to direct evidence in Purdue's Adverse Event Reporting Database that showed specific instances of exactly the same congenital malformations warned of in the National Birth Defect Prevention Study.

78. McKinsey achieved the intended result of its lies. No warnings about congenital malformations, birth defects, teratogenic effects or fetal-embryo toxic effects ever made it into PSUR for the FDA or the labeling materials provided to doctors. Further, language remains to this day that falsely states: "There is no available data with OxyContin in pregnant women to inform a drug-associated risk for major birth defects and miscarriage."

79. With certain audiences, however, McKinsey admitted the truth. In a series of presentations to governments and insurance companies, McKinsey listed the exact congenital malformations that the National Birth Defects Prevention Study listed as being related to in utero exposure to opioids. An example is [redacted]

[redacted]

D. Client Engagement No. 4: McKinsey's Skillful Use of Contract Research Organizations to Support Its Clients' False Claims

80. McKinsey was the architect of an important vehicle for perpetuating false and misleading data to the FDA, consumers, and prescribers. McKinsey encouraged its clients to use hand-selected, pre-screened researchers and scientists—contract research organizations or "CROs"—to perform the analyses needed for FDA approval of opioid drugs. In some cases, McKinsey itself cherry-picked data from prior experiments conducted by its clients and sent the data directly to its pre-screened researchers and scientists.

[redacted]

81. McKinsey ghostwrote articles in peer-reviewed journals presenting the findings of these CROs as non-biased and scientifically sound. McKinsey also analyzed, wrote, and packaged FDA New Drug Applications for their opioid manufacturing clients to gain FDA approval for new opioid drugs. McKinsey used its ghostwritten articles and scientific analyses to bolster the

safety and efficacy claims of their client's drugs to gain FDA approval, or simply to sell more drugs. McKinsey's work on this science was never disclosed to journals, regulators, or the public.

82. McKinsey specifically orchestrated the targeting of medical journals, insurance companies/payors, and healthcare professionals for information and research on safety, efficacy, and abuse. This included executing proactive outreach activities to patients and doctors, identifying key opinion leaders in the medical community, and identifying health economics policy informatics data. McKinsey crafted medical messaging for opioid products that was false and misleading.

83. One relatively well-known example includes McKinsey's skillful manipulation of data supporting Purdue's registration of ADF OxyContin and its claim that pain relief from ADF OxyContin lasts 12 hours. Having convinced Purdue to send this and all other research to McKinsey's hand-picked scientists, McKinsey then oversaw and rode those scientists, micromanaging everything from study design to data analysis.

84. By the time Purdue sought regulatory approval for ADF OxyContin, it was an open secret that the analgesic effects of OxyContin lasted only eight hours for most patients. In fact, [redacted]

[redacted]

85. McKinsey orchestrated and oversaw studies designed to capitalize on this common practice, and support the 12-hour claim in ADF OxyContin's registration, by turning OxyContin's well-known weakness—that it does not last 12 hours and so other opioids must be given with it—into a strength. [redacted]

86. McKinsey knew that ADF OxyContin did not provide the claimed benefit of 12-hour pain relief, but intentionally rigged studies conducted by CROs that it oversaw and controlled so Purdue could make that claim and sell more pills.

87. These specific client engagements are merely illustrative not exhaustive. Plaintiffs anticipate that many more specific examples of this kind of behavior will emerge with the opportunity for additional discovery.

VII. GENERAL ALLEGATIONS OF MCKINSEY'S CONTROL OF THE OPIOID CRISIS

88. There is not one aspect of the opioid crisis that McKinsey[27] did not design, oversee, implement, and control. Beginning in at least the 1990s, McKinsey was the mastermind behind the opioid crisis. McKinsey created the Industry of Pain. It was not routine consulting—it was the McKinsey Way. It is the McKinsey Opioid Epidemic.

89. In this Amended Complaint, Plaintiffs set forth the actions that McKinsey directly took to control, manipulate, and abuse the opioid market itself that resulted in the injuries suffered by Plaintiffs:

- McKinsey knew OxyContin and other extended-release drugs did not last for the 12-hour dose, which was the entire basis for FDA approval of long-acting opioid drugs, as well as the basis for targeting opioids prescribing by healthcare providers
- McKinsey knew precisely how abused OxyContin and other opioids were because it calculated how many doses each patient received at each dosage level and then instructed its co-conspirators to abuse the abuse by making more money by targeting those high dose patients and converting them to even higher doses
- McKinsey exploited and helped increase the opioid abuse epidemic in order to push abuse so high that the FDA would require abuse deterrent formulations and give exclusive sales rights to McKinsey's clients
- McKinsey constructed algorithms to identify prescribers to target with an onslaught of sales representatives—this went well beyond McKinsey merely pulling numbers of total opioid prescriptions per doctor
- McKinsey's data showed pregnant women were being diagnosed with Opioid Use Disorder while pregnant at alarmingly high rates
- McKinsey instructed multiple co-conspirators to pair opioid pain drugs with drugs targeted to specific conditions for women of childbearing age and ability, utilizing conspirators existing OBGYN pain targeting relationships—those conditions included those trying to get pregnant through In Vitro Fertilization (IVF)
- McKinsey's self-touted expertise in women's health (in general) and specifically maternal health included identifying how crucial OBGYNs

[27] As described later in the section on the parties, collectively, the Defendants are referenced as "McKinsey."

were to women taking opioids during pregnancy and NAS outcomes, stating to state Medicaid clients that if Medicaid targeted OBGYNs to stop opioid usage, maternal opioid usage would decline—while telling opioid manufacturers to target OBGYNs for opioid sales

- McKinsey not only targeted OBGYNs for opioid sales, but refused to remove OBGYNs from the target lists when requested by sales representatives
- McKinsey knew fetal opioid exposure increases the risk of long-term injuries, including developmental and behavioral problems, neural tube defects, congenital heart defects, and gastroschisis, in addition to the concerns for pre-term birth, stillbirth, and withdrawal at birth
- McKinsey designed clinical studies, handled clinical data, interpreted data analyses, and ghostwrote scientific journal articles, as well as key crucial submissions to the FDA

90. McKinsey had a duty not to promulgate lies that harm Plaintiffs; mislead the FDA about the safety and efficacy of opioid drugs; and escalate abuse and diversion by manipulating systems with conspirators to encourage abuse and diversion of opioids, particularly by prescribers.

91. Over a span of decades McKinsey implemented a scheme to manipulate the Opioid Market on behalf of its' Opioid Clients to use its pivot position between the major manufacturers, Contract Research Organizations (CROs), the distributors, the FDA, third party payors and state governments; such Opioid Market Manipulation was not only knowingly violative of the Controlled Substances act, but also performed in a manner that aided and abetted its clients' efforts to hide their products addictive nature and harm to the unborn, causing proximate harm to the Plaintiffs pled herein.

92. With Purdue, McKinsey designed and executed projects to target never-ending increases of prescribing by healthcare professionals—plans that were then continuously reevaluated and micromanaged to increase even more sales. McKinsey targeted health care facilities in order to reach larger audiences of unnamed healthcare professionals. Upon information and belief, this relationship between Purdue and McKinsey would continue well up to Purdue's bankruptcy.

93. McKinsey targeted health insurers/payors to increase coverages of branded opioid drugs to increase branded sales, using its contacts in the industry, particularly as other clients of the consulting firm, to help persuade insurers/payors to continue funding the opioid crisis, increasing the flood of prescription opioids.

94. McKinsey is architect of the vehicle to perpetuate false and misleading data for the FDA and health care providers. McKinsey had its hand-selected researchers and scientists perform analyses needed for FDA approval of opioid drugs, it directly sent the researchers and scientists experimental sample data provided by the manufacturers themselves, and ghostwrote articles in peer-reviewed journals presenting these findings as non-biased and scientifically sound. McKinsey then analyzed, wrote, and packaged FDA New Drug Applications for their opioid manufacturing clients to gain FDA approval for new opioid drugs. McKinsey used its ghostwritten articles and scientific analyses to bolster the safety and efficacy claims of their client's drugs to gain FDA approval. McKinsey's work on this science was never disclosed to journals, regulators, or the public.

95. McKinsey specifically orchestrated the targeting of medical journals, insurance companies/payors, and healthcare professionals for information and research on safety, efficacy, and abuse. This included executing proactive outreach activities to patients and doctors, identifying key opinion leaders in the medical community, and identifying health economics policy informatics (HECON) data. It crafted the medical messaging for opioid products that was false and misleading.

96. McKinsey targeted deals with large healthcare facilities to ensure that places like large hospitals would continue to contract for large orders of McKinsey's clients' opioid drugs.

97. McKinsey identified [redacted].[28]

[28] MCK-MDL2996-0610243.

98. McKinsey did what the pharmaceutical industry itself could not directly do—engage in anticompetitive practices through collusion. McKinsey had access to more data than any other actor in the Opioid Crisis: datasets on sales, discounts, and pricing that McKinsey had access to from its various pharma and regulatory client projects were shared and combined to form a McKinsey common database—including McKinsey's own Field Guide, as well as marketing and sales data—that McKinsey then manipulated, depending on the schemes it was working on at the time.

99. Beyond the multiple "Turbocharge" sales strategies designed to expand the opioid market without limit, McKinsey's other schemes to increase opioid sales involved more than just proffered advice to opioid clients. It concocted elaborate schemes, implemented those schemes, oversaw the project, evaluated the success of those executed schemes, provided continuous improvement on those schemes, and adjusted the schemes to further provide feedback. McKinsey was also an essential step in executing those schemes—in many instances, McKinsey was the actual scheme. McKinsey was an essential, "tremendous contribution" to the entire venture, as their co-conspirators stated.

100. McKinsey knew opioid drugs were highly addictive and being diverted. Because McKinsey had data on total opioid sales by molecule across the industry, including the number of total prescriptions filled by patients, the dosage by milligram strength, and the total morphine milligram equivalents (MME) taken per patient, McKinsey knew 1) that OxyContin was not effective for 12 hours and 2) that the enormous number of pill patients were prescribed indicated patients were taking far more than the maximum 12-hour dosage. McKinsey knew this because [redacted]

[redacted]

101. There were giveaways to doctors of analog clocks branded with OxyContin because it was supposed to last 12 hours like a 12-hour analog clock. There are only two conclusions McKinsey could draw from this: the drug was not working as described for nearly 3 out of 4 patients, enormous numbers of pills were being diverted—particularly because the pills did not work for 12 hours, leaving patients in pain or with withdrawal symptoms and needing more pills—or both. There is no doubt that both were happening.

102. McKinsey crafted a multilevel approach to target doctors and healthcare facilities to increase sales. Through sales calls, drug sales representatives would target prescribers to increase the number of prescriptions written for opioids, particularly the clients' brands. McKinsey calculated the type and volume of each health care provider prescribing opioids in the U.S. and sorted them into deciles based on total prescriptions filled by patients. McKinsey then crafted its own criteria to determine who to specifically target. For example, these were often based on types of opioids prescribed (long-acting versus short-acting, generic versus branded), region (trending zip code areas where sales were increasing in the country), how the typical

patient of the prescriber pays for his or her prescription (by specific insurance company, Medicare, or cash) type of prescriber (physician assistants and nurse practitioners began increasing prescribing when other healthcare professionals declined), and specialty of prescriber (including specifically including OBGYNs). This was driven largely by total prescriptions but included nuanced analyses as well. McKinsey then instructed the co-conspirator opioid manufacturers to target the highest deciles because the data showed these doctors were most likely to increase prescriptions after being targeted and then McKinsey instructed the co-conspirators on how to target that doctor, down to the specific number of sales calls/visits, unique to each prescriber.

103. McKinsey would then follow-up and evaluate the success of the sales representative's efforts and then adjust for the next target period. [redacted][29]

104. Turbocharging opioid prescribing by targeting prescribers was not all McKinsey did to manipulate the opioid market. McKinsey subverted peer-reviewed scientific journals to manipulate the FDA, doctors, insurance companies/payors, and the public. In addition to ghostwriting articles, [redacted]

[29] MCK-MDL2996-0245217.

[redacted][30]

105. The particularly insidious nature of the ADF collusion is that it interfered with the FDA's attempts to curb abuse and fight the McKinsey Opioid Epidemic. [redacted][31]

106. McKinsey concocted a scheme by which [redacted]

[30] MCK-MDL2996-0083374.
[31] MCK-MDL2996-0114459.
[32] MCK-MDL2996-0104521.

[redacted] Upon information and belief, this ADF scheme was implemented by McKinsey and opioid manufacturers.

107. McKinsey admits [redacted][33]

108. Pregnant women and fetuses are considered special populations by the FDA for drugs. Because of the considerable health concerns for these two groups, the FDA requires drug manufacturers to consider those special injuries that can occur to fetuses during gestation and neonatally when exposed to drugs in the womb.

109. The special injuries to FOE children are different from the kinds suffered by any other victims of the McKinsey Opioid Epidemic. They are beyond the harms caused by the nuisances caused by the McKinsey and inflicted upon the general public. These special injuries are separate and apart from "addiction," opioid use disorder (OUD), medical dependency, and the harms caused by OUD and/or addiction to governmental and public entities for injuries like increased policing, response costs for overdoses, and costs to the medical system. These children will suffer from these injuries for the rest of their lives, and it will continue to impact the quality of their lives. These special damages are lifelong and separate and apart from addiction, OUD, and the harms caused by OUD and/or addiction. Moreover, not only were they foreseeable, these harms were in fact foreseen, understood, and appreciated by McKinsey.

110. McKinsey told co-conspirators [redacted].[34] [redacted]

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[33] Two examples from the limited discovery already conducted in this litigation are MCK-MDL2996-0988313 and MCK-MDL2996-0070516.

[34] An example from the limited discovery in this litigation is MCK-MDL2996-0104896.

[redacted]

111. OBGYNs play a vital role of overseeing the health of the pregnancy, including fetal health. [redacted][35] [redacted]

112. [redacted][36] [redacted].[37] [redacted][38] [redacted]

[35] An example from the limited discovery in this litigation is MCK-MDL2996-1225320.
[36] An example from the limited discovery in this litigation is MCK-MDL2996-046717.
[37] An example from the limited discovery in this litigation is MCK-MDL2996-0988313.
[38] An example from the limited discovery in this litigation is MCK-MDL2996-0610566.

[redacted][39]

113. McKinsey acknowledges that [redacted].[40] [redacted] Significantly, McKinsey itself acknowledges [redacted][41] These misguided beliefs are directly due to McKinsey's own tortious actions in the manipulation of scientific data, misleading the FDA, and driving the increased prescribing by doctors.

114. All humans, including pregnant women, have a right to autonomy when making healthcare decisions, including what drugs to take or decline. The cornerstone of informed consent is being provided with, as well as understanding, the risks and benefits of taking any medication. The pregnant woman makes decisions for her fetus as it develops into a baby. When a risk to her baby's health is not disclosed to a pregnant woman, her autonomy is destroyed. When a risk to her baby's health is hidden or wholly disregarded for the purposes of drug manufacturer profits, no autonomy exists. No baby is safe in a world when profits trump informed consent.

[39] An example from the limited discovery in this litigation is MCK-MDL2996-0610566.
[40] MCK-MDL2996-0624376.
[41] MCK-MDL2996-0624376.

115. McKinsey and its co-conspirators chose to make the decisions of risk and health to unborn babies for the mothers. It took decisions out of the hands of the FDA and doctors, and it took those decisions out of the hands of the birth mothers. McKinsey chose billable hours over children's health.

116. Incredibly, [redacted][42]

117. Pregnant women relied upon the information provided to them—or the lack of critical information about long-term impacts—about taking opioids during pregnancy. Despite a quarter of a century of increasing numbers of children exposed to opioids in the womb, a plethora of human epidemiology and biological science research tailored specifically to concerns about fetuses and children, and reported actual adverse events from pregnant women who took the drugs (or their doctors) reported to the FDA and opioid industry, there are no warnings about the long-term impacts to babies exposed to opioids in the womb. McKinsey was aware of or should have been aware of the growing science about FOE. McKinsey directed at least 3 critical large-scale branded opioid drug campaigns (including the reformulated OxyContin) for submission to the FDA *in the height of the NAS/FOE epidemic* and did not reflect any of those issues—such as the birth defects, the behavioral issues, and developmental problems—in the special population sections of any of the FDA-required warnings. McKinsey directed the science for these drug applications, analyzed the results, drafted the applications, directed consultants on what to say, and prepared the entire NDA presentations for the manufacturers.

118. McKinsey's turbocharging of the opioid market wasn't merely routine consulting; it was a calculated conspiracy to evade the Controlled Substances Act to use suspicious prescribing practices that should have been flagged as suspicious ordering to instead use those healthcare providers to increase sales. McKinsey identified the most suspicious prescribers because it was most likely that those prescribers would—with specific actions taken by the manufacturers at the behest of McKinsey—become even more suspicious by prescribing in ever increasing amounts. McKinsey then utilized all the information and sources at its command to

[42] MCK-MDL2996-0079606.

show how highly successful following McKinsey's orders were and crafted more instructions to follow or sales would decline.

119. McKinsey knew the increased turbocharged sales were effective in turbocharging the illicit diversionary market because it accessed data [redacted][43] [redacted].[44] However it continued to identify and target prescribers based on regions where sales were high or when efforts by states and localities were successful to reduce abuse, McKinsey specifically targeted those regions as necessary to regain sales.

120. McKinsey's control was absolute because opioid manufacturers knew that their specialized information was for sale by McKinsey to competitor opioid manufacturers, and that if any of them didn't follow McKinsey's orders, the competitors would use that data from McKinsey to then steal market share. To maintain market share, each manufacturer had to continuously implement McKinsey's orders, resulting in the turbocharging of opioids prescribed to the public. McKinsey oversaw the simultaneous turbocharging of the opioid market at both a highly micromanaged level, as well as a large, broad market view. Thus, the McKinsey Opioid Epidemic escalated.

121. Plaintiffs allege that McKinsey's design, implementation, and oversight of its manufacturing clients' new drug application process negligently and intentionally hid from regulators and health care providers information about the risk of congenital birth defects and embryo-fetal toxicity.

122. Plaintiffs allege that McKinsey designed, implemented, and oversaw physician targeting of their mothers' doctors by multiple McKinsey opioid manufacturer clients.

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[43] MCK-MDL2996-0427452
[44] MCK-MDL2996-0226924

123. Plaintiffs E.A.B., A.A., K.A., and R.R. allege their mothers did not suffer from Opioid Use Disorder, that their mothers were taking non-MAT opioids for pain relief during pregnancy, that they all suffered from In Utero Opioid Exposure (IUOE), that they were all born with Neonatal Abstinence Syndrome (NAS), that they each suffered from congenital birth defects related to IUOE, that McKinsey was aware of such risks and that, in the design, implementation, and oversight of its Opioid Clients' new drug applications and marketing, McKinsey hid such risks from the FDA, their mothers' doctors, and their mothers.

124. Plaintiffs Z.D.B.B., M.L., E.G.W., J.V., and M.V. allege their mothers became addicted to prescription opioids sold and distributed by McKinsey's clients, that their mothers were taking prescribed Medication Assisted Treatment opioids (MAT) to manage their addiction during pregnancy, that were all born with NAS, that they each suffered from cognitive/behavioral issues directly related to IUOE, they each suffered from physical injuries directly related to IUOE, that McKinsey was aware of such risks and that McKinsey's acts and omissions undertaken in concert with its opioid clients caused Plaintiffs injuries by hiding the true risks of IUOE from the FDA, their mothers' OBGYNS, and their mothers, and by implementing an industry-wide collusive marketing schemes that ultimately addicted their mothers.

125. McKinsey, as a "Covered Person" owed a duty to the infant victims of the Opioid Crisis before the Court to adhere to the terms of the Corporate Integrity Agreement entered into after the 2007 Purdue Guilty Plea.

126. McKinsey owed a duty to the infant victims of the Opioid Crisis before the Court to not promulgate lies and manipulate the Opioid Market in violation of the Controlled Substances Act.

127. McKinsey owed a duty to the infant victims of the Opioid Crisis to not promulgate lies and manipulate the Opioid Market in a manner intended to deceive law enforcement, regulators, doctors, scientific researchers and women consumers of Opioids.

128. McKinsey designed and implemented a regulatory manipulation scheme assisting opioid manufacturers with new drug applications and FDA submissions, while skirting increased scrutiny as the opioid epidemic worsened.

129. McKinsey designed and implemented a scientific manipulation scheme:

a. to hide the addictive nature of its clients' drugs, which proximately caused the addiction of the birth mothers described in this complaint.

b. to hide the long-term damage done to infants in the wombs.

130. McKinsey capitalized on its long-standing relationships to design and implement the manipulation of the Opioid Market that grew the Opioid Market in contravention of the letter and spirit of the Controlled Substances Act.

131. McKinsey is liable for its misconduct and the harms it caused or exacerbated. McKinsey is liable for its successful efforts to increase opioid sales for years. It continued this work unabated and with alacrity despite events as stunning as Purdue's 2007 guilty plea for misbranding OxyContin, Purdue's 2015 settlement with the State of Kentucky, and numerous other enforcement actions related to opioid sales and marketing by McKinsey clients. It executed work that fueled the fetal opioid exposure crisis. It executed work that fueled the overdose crisis. Through it all, McKinsey remained steadfast in its efforts to turbocharge opioid sales for all of its clients for the purpose of maximizing return on investment without regard to the obvious implications of what they were doing. Indeed, the firm endeavored alongside its clients to increase the size of the *overall* opioid market for *over two decades*, until as late as March 22, 2019, despite increasingly blood-red flags along the way.[45]

VIII. HARM CAUSED TO NAS PLAINTIFFS

A. Harm to Babies Who Suffered from In Utero Opioid Exposure Extend far Beyond the Acute Impacts of Neonatal Abstinence Syndrome

132. The impacts and causes of NAS are so obvious as to be undeniable, and in fact McKinsey and its clients have acknowledged in new drug applications, labels, and marketing materials that IUOE causes NAS but downplay the severity of the condition by pointing out that NAS is treatable and lie about long-term impacts like congenital malformations, brain damages, heart defects, cognitive deficits, and behavioral issues. When an expectant mother takes opioids

[45] *See* "About McKinsey's past work for opioid manufacturers," *last updated March 22, 2021*, *available at:* https://www.mckinseyopioidfacts.com ("We decided nearly two years ago to end all work on opioid-specific business ….").

during pregnancy, the drugs pass through the placenta and cause serious problems for a fetus that go far beyond opioid withdrawal and include congenital malformation and other long-term injuries for which doctors and mother never received warnings.

133. Videos on the evening news of opioid exposed newborns screaming, writhing, and convulsing after the cutting of the umbilical cord vividly illustrate the some of the constellation symptoms of opioid withdrawal that make up Neonatal Abstinence Syndrome.

134. Neonatal abstinence syndrome, also called neonatal opioid withdrawal syndrome ("NOWS"), is a group of conditions caused when babies withdraw from certain drugs, most commonly opioids, they're exposed to in the womb before birth.

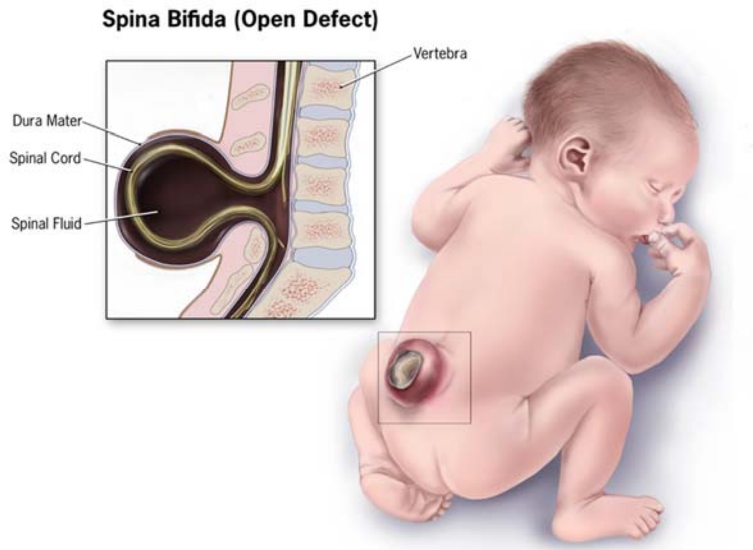
135. Infants born with NAS often exhibit symptoms of opioid withdrawal including tremors, seizures, overactive reflexes, and tight muscle tone; fussiness, excessive crying or having a high-pitched cry; poor feeding or sucking or slow weight gain; breathing problems; fever, sweating, or blotchy skin; trouble sleeping and lots of yawning; diarrhea or vomiting; and stuffy nose or sneezing.

136. Infants born with NAS may be treated with medications such as morphine, methadone, or buprenorphine to manage withdrawal symptoms.

137. Babies with NAS are more likely to require treatment in the neonatal intensive care unit ("NICU").

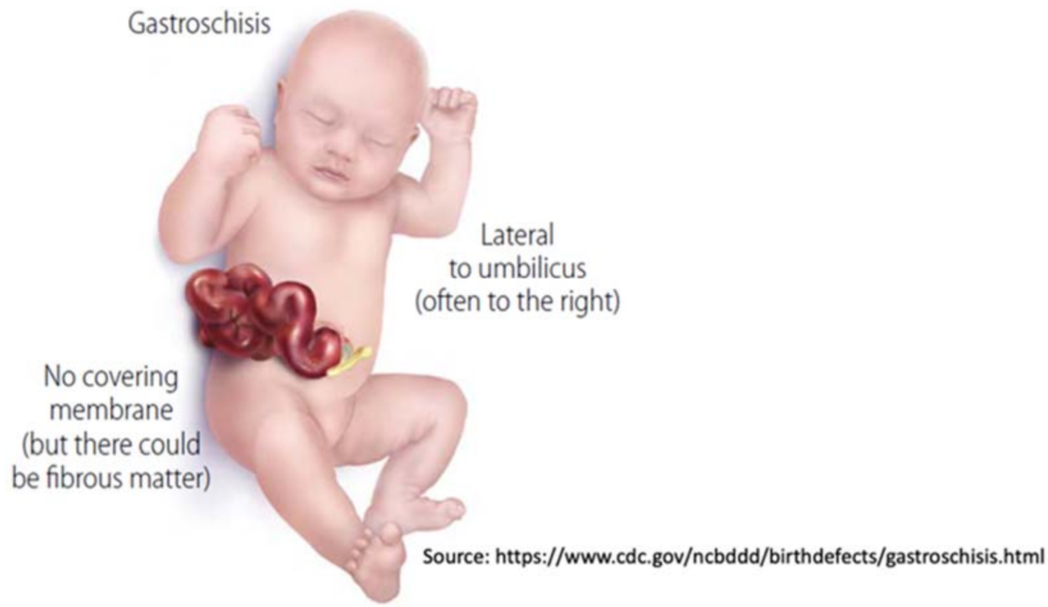
138. They are also at increased risk of being born prematurely, low birthweight, jaundice (which is evidence of liver problems), seizures, respiratory issues, sudden infant death syndrome, and other birth defects.

139. The majority of opioid receptors are located in the gastrointestinal tract and central nervous systems. As a result, the impacts of prenatal exposure often manifest with injuries to the gastrointestinal and central nervous systems. This includes both short-term and long-term injuries.



Source: https://upload.wikimedia.org/wikipedia/commons/7/7e/Spina-bifida.jpg

Source: https://www.cdc.gov/ncbddd/birthdefects/surveillancemanual/chapters/chapter-4/chapter4.9a.html



140. There are two types of injuries suffered by children prenatally exposed to opioids—short-term injuries related to withdrawal at birth, and long-term injuries related to the exposure alone (with or without withdrawal at birth). Separating children born with NAS who face some of the same withdrawal symptoms as adults addicted to opioids is the fact that IUOE disrupts the physical development of the fetus, causing long-term impacts like brain damage, congenital malformations, heart defects, developmental delays, motor problems, behavior and learning problems, emotional disorders and other psychological symptoms, speech and language problems, sleep issues, ear infections, and vision problems.

141. Plaintiffs' fetal toxicology expert, Dr. Vyvyan Howard, explains the process: Opioid exposure in the womb increases the rate of apoptosis, or cell death, in the unborn fetus, leading to fetal malformations, including NAS and birth defects. Dr. Howard explains, "Opioids have been shown to perturb the rate of apoptosis in development1 and this is the most likely common mechanism for the fetal malformations reported in Broussard et al (2010). It will also occur at very low opioid concentrations." *See* Decl. of Dr. Vyvyan Howard (June 20, 2020).

142. According to well-designed scientific studies, there is an established link between this process of opioid exposure related apoptosis and the development of birth defects in the

womb, including gastroschisis, spina bifida, cleft palate, and club foot, among others. Dr. Howard explains the process and scientific findings thusly:

> *"Evidence that opioids behaved as they were predicted to and caused major birth defects appeared in the results of the National Birth Defect Prevention Study published in 2010 (Broussard et al, 2011; McCarthy, 2015). The study looked at 17,449 cases and 6701 controls. Statistically Significant effects were found for associations between early pregnancy maternal opioid analgesic treatment and certain birth defects, notably heart defects, anencephaly, cleft palate and spina bifida."*

Dr. Howard 2020 Decl. at 12.

143. Dr. Howard further states that research showing the ability of opioid drugs to disrupt fetal development through apoptosis was well known in early studies of OxyContin, conclusions which were ignored by Purdue in the creation of their early warning labels. Dr. Howard explains that, by 2010, the Broussard Study made the link between fetal malformations and opioid exposure in the womb even clearer, yet this study was also ignored by Purdue, meaning that safety of opioid drug use in pregnant women was never established in the medical literature.

144. An independent board-certified neonatologist with 31 years of experience, Dr. James Hocker prepared an expert opinion at the request of the Trustee of the Purdue Pharma Personal Injury Trust Settlement[46] to "express an opinion on whether the appearance of these ICD codes (ICD codes suggested by Purdue Bankruptcy Ad Hoc Committee for NAS Claimants) in a Claimant's… medical records is a reasonable basis to make a conclusion that the Claimant experienced in utero opioid exposure."

145. Dr. Hocker relied on material that upon information and belief was in the possession or knowledge of McKinsey at all times relevant including: 1) internal Purdue scientific documents, 2) Purdue's Periodic Safety Update Reports, 3) OxyContin HCI Adverse Events Report, 4) New Drug Applications, 5) CCDS collections for oxycodone, hydromorphone and buprenorphine, 6) Opidol Product Characteristics Summary, 7) Assessment of NAS surveillance

[46] Approximately 9,000 NAS children filed proof of claim forms in the Purdue Pharma bankruptcy proceeding according to publicly available Kroll data, a relatively small number given a $26 million ad campaign. Upon information and belief, roughly half of those claims will be eligible for an award.

in Pennsylvania, 8) information from a large maternal infant data hub, 9) Plaintiff expert reports, and 10) 12 peer-reviewed articles from medical journals.

146. Dr. Hocker's conclusions linked the following congenital malformations or birth defects to IUOE and listed associated applicable ICD codes:

- Arnold Chiari Brain Malformation
- Club Foot
- Cerebral Palsy
- Cleft Palate
- Congenital Deformation
- Gastroschisis
- Hearing Problems
- Heart Defects
- Missing or Additional Fingers and Toes
- Serious Vision Problems
- Spina Bifida (and other neural tube defects)

147. Dr. Hocker's conclusions linked to IUOE the following long-term impacts on development and listed associated applicable ICD codes:

- Attention problems/Inability to Focus (including ADD & ADHD)
- Learning Disability/Cognitive Delays
- Oppositional Defiance Disorders
- Social/Behavioral Difficulties or Delays
- Autism
- Delay or Inability to Talk
- Delay or Inability to Walk
- Depression
- Growth Developmental Delays

148. Dr. Hocker's conclusions linked to IUOE the following other impacts not listed above and listed associated applicable ICD codes:

- Stillbirth
- Premature Birth
- Hospital Length of Stay
- Respiratory Problems
- Unexplained Acid Reflux
- Difficulty Swallowing, Breastfeeding or Bottle-Feeding

149. McKinsey and its clients knew, or should have known, of the risks and harms of fetal opioid exposure but suppressed this information, thereby depriving doctors, women, parents, scientists, and regulators of critical information. The artificial increase in supply of opioids driven by McKinsey and its clients led women of child-bearing age, and pregnant people alike, to become addicted, stay addicted, and, ultimately, expose their fetuses to opioids.

150. In particular, McKinsey was in a position to have access to Purdue's comprehensive and highly-sophisticated and detailed life sciences library consisting of, for instance, volumes of Company Core Data Sheets ("CCDS") (from at least 2000-2017) containing whole sections with entries for fertility, pregnancy and lactation. McKinsey also had access to reams of manufacturers' adverse event reports documenting a wide range of birth defects resulting from fetal opioid exposure, including brain stem malformations, digestive tract malformations, heart defects, skeletal malformations, spina bifida, and cleft palate.

151. McKinsey was privy to, collaborated with, and enabled internal manipulation of scientific studies related to the risks and harms posed by Purdue's opioid products. For example, over the years, language found in Purdue's warning labels and CCDS regarding potential reproductive dangers of their drugs, in particular NAS and NOWS, changed drastically. [redacted].[47] [redacted]

[47] *See* PURCHI-000572404, 1994 Archival New Drug Application. [2804]

[redacted][49] By virtue of McKinsey's familiarity and work in connection with Purdue's research and development and regulatory processes, McKinsey would have been aware of changes to entries contained in Purdue's CCDS for oxycodone and other opioid products.

152. McKinsey could have, and should have, included warnings for the prescribing of opioid drugs during pregnancy in its opioid marketing plans.

B. Specific Harm to Plaintiffs

1. Katrina Cox and K.A.

153. Katrina Cox is the biological mother of K.A., born April 29, 2016 at Methodist Hospital South in Memphis, Tennessee. K.A. was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

154. Ms. Cox was prescribed oxycodone, hydrocodone, and Percocet (manufactured by McKinsey client Endo) after breaking her pelvis and injuring her hand in a car accident around 4 months into her pregnancy with K.A. Her prescribing physician was Dr. Andrew Holt and her OB-GYN was Dr. Stephen Ehiremen. Dr. Ehiremen was targeted by McKinsey, appearing on at least one McKinsey target list. Upon information and belief, Dr. Andrew Holt was targeted by McKinsey as well.

155. Ms. Cox was not an addict; her opioid prescription was for treatment of her pain, not to treat addiction. She was not prescribed and did not ingest Medication-Assisted Treatment drugs (MAT) prior to or during her pregnancy with K.A.

156. As a result of her in utero opioid exposure from these prescriptions, K.A. was born with club foot, with both of her feet twisting inward. Her struggles with club foot have required years of therapy to allow her to walk, and she still struggles with putting shoes on her feet and doing other normal physical activities. She also suffered other leg issues, an ear deformity requiring surgery at 6 months, attention issues, a delayed ability to talk, social/behavioral

[48] *See* PKY180604976, 1997 Archival New Drug Application for Oxycodone. [2804]
[49] *See* PPLPC013000063753, 2000 Company Core Data Sheet, Oxycodone Hydrochloride. [2804]

difficulties, depression and anxiety/panic attacks, and respiratory and vision problems. She has suffered from neurological tremors her entire life, which make it difficult for her to sleep.

157. As a result of exposure to opioids in utero, K.A. suffered the following special injuries:

- Club foot
- Hearing defects requiring surgery of her ear tubes
- Serious vision issues
- Respiratory issues
- Attention problems
- Delayed ability to talk
- Depression and anxiety
- Social/Behavioral difficulties

158. Had Ms. Cox known of the risk that these injuries can be caused by in utero opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

2. <u>Sarah Riley and E.A.B.</u>

159. Sarah Riley is the biological mother of E.A.B., born on August 30, 2005 at Logan Regional Hospital in Logan, Utah. E.A.B. was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

160. About four years before becoming pregnant with E.A.B., Ms. Riley was prescribed Nubain for her migraine headaches and pain related to EDF syndrome, a rare genetic tissue syndrome affecting her joints. Her doctor, Dr. Kevin Duke, and her perinatologist Dr. Gary Fowers continued to provide her Nubain (manufactured by McKinsey client Mallinckrodt) throughout her pregnancy with E.A.B., telling her there were no risks of harm to her or the fetus.

161. Upon information and belief, Dr. Duke and Dr. Fowers were targeted by McKinsey.

162. Ms. Riley was not an addict- her opioid prescription was for treatment of her pain, not to treat addiction. She was not prescribed and did not ingest Medication-Assisted Treatment drugs (MAT) prior to or during her pregnancy with E.A.B.

163. As a result of this in utero opioid exposure from these prescriptions, E.A.B. was born premature with spina bifida neural tube defect, a birth defect that occurs when the spine and spinal cord do not form properly. Specifically, E.A.B. was born with a hole in his L5 vertebrae, requiring 2 spinal fusion surgeries. E.A.B. spent 14 days in the NICU after birth. He is almost deaf in his right ear. He struggles with double vision. He also suffered a learning disability requiring an IEP, developmental delays, serious respiratory problems, ADHD, and other long term health problems.

164. As a result of exposure to opioids in utero, E.A.B. suffered the following special injuries:

- Spina bifida/neural tube defect
- ADHD
- Developmental delays
- Learning disability
- Depression
- Hearing problems
- Respiratory problems
- Vision problems
- 14 days in NICU

165. Had Ms. Riley known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to

McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

3. Brandi Shatnawe and A.A.

166. Brandi Shatnawe is the biological mother of A.A., born on November 22, 2010 at Integris Baptist Medical Center in Oklahoma City, Oklahoma. A.A. was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

167. Ms. Shatnawe's dentist, Dr. Lee Eliot, prescribed her Lortab and Darvocet (manufactured by Xanodyne Pharmaceuticals) about a week before she found out she was pregnant with A.A. to treat pain from a root canal. She continued to take opioids for the first several weeks of the pregnancy, exposing A.A. to opioid in utero.

168. Neither Dr. Eliot nor Dr. Bhoplay warned her of the risks of ingesting opioids during pregnancy. Dr. Eliot was targeted by McKinsey, appearing in at least one McKinsey target list. Her OB-GYN, Dr. Vinay Bhoplay, was also targeted by McKinsey, appearing in at least one McKinsey target list.

169. Ms. Shatnawe was not an addict- her opioid prescription was for treatment of her pain, not to treat addiction. She was not prescribed and did not ingest Medication-Assisted Treatment drugs (MAT) prior to or during her pregnancy with A.A.

170. As a result of this in utero opioid exposure, A.A. was born premature with gastroschisis, a birth defect where a hole in the abdominal (belly) wall beside the belly button allows the baby's intestines to extend outside of the baby's body. This severe birth defect required the removal of his intestines, and they are currently seeking a small intestine transplant. A.A. was not breathing when he was born, and spent 210 days in the NICU. To this day, he is unable to eat, requiring that he be fed intravenously. He vomits frequently, suffers severe diarrhea and has to have his stomach drained. He also continues to suffer developmental issues, frail bones, serious near-sided vision and a lazy eye.

171. As a result of exposure to opioids in utero, A.A. suffered the following special injuries:

- Gastroschisis and related severe digestive issues

- Growth/Developmental Delays
- Severe Vision Problems
- 210 days in NICU

172. Had Ms. Shatnawe known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have continued taking these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

4. <u>Hayden Travis Blankenship and Z.D.B.B.</u>

173. Hayden Travis Blankenship is the biological father of Z.D.B.B., who was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

174. Z.D.B.B.'s biological mother was prescribed a variety of opioids before and during her pregnancy with Z.D.B.B., including but not limited to hydrocodone with acetaminophen, oxycodone with acetaminophen, and OxyContin (manufactured by McKinsey client Purdue). While pregnant with Z.D.B.B., she also used opioids obtained from the illegal diversionary market.

175. McKinsey targeted Dr. Michael Crews, who prescribed Z.D.B.B.'s biological mother hydrocodone and acetaminophen tablets between 2012 and 2013 and Oxycodone and Acetaminophen tablets between 2012 and 2015, prior to Z.D.B.B.'s birth. Dr. Crews appeared in at least one McKinsey target list, in 2011 as a mid-decile prescriber. Her OB-GYN, Dr. Brandon Lingenfelter, who prescribed her methadone during pregnancy, was also targeted by McKinsey, appearing in at least one target list in 2017 as a mid-decile prescriber.

176. Z.D.B.B. was exposed to opioids in utero and was born three months prematurely on May 29, 2017 at Princeton Community Hospital in Princeton. WV. Z.D.B.B. was diagnosed with NAS at birth and was transferred to the NICU at CAMC Women and Children's Hospital in Charleston, WV. Z.D.B.B.'s medical records from the NICU show that he experienced

intrauterine growth restriction, maternal methadone usage, tachypnea, respiratory distress requiring oxygen at 35%, hepatitis C, high-pitched and excessive crying, increased muscle tone, myoclonic jerks, mottling, loose stools, hypertonic motor reflexes, mild tremors, excoriation, persistent NAS-related fevers, increased and abnormal respiratory rate, and difficulty feeding requiring a nasogastric tube and parenteral nutrition.

177. As a further result of exposure to opioids in utero, Z.D.B.B. suffered the following special injuries:

- Vision problems
- Respiratory issues
- Irritable bowel problems
- Chronic diarrhea and gastrointestinal problems
- Attention problems and inability to focus
- Depression
- Learning disabilities and cognitive delays
- Social and behavioral difficulties
- 30 days in NICU

178. Upon information and belief, had Z.D.B.B.'s birth mother known of the risk that these injuries that can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

5. <u>Marina Brizendine and S.B.</u>

179. Marina Brizendine is the biological mother of S.B., who was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

180. Ms. Brizendine was first prescribed OxyContin around 2005 for chronic pain related to a preexisting knee injury. She continued to be prescribed opioids, including OxyContin and Norco, through 2019, including during her pregnancy with S.B., to manage her pain due to

carpal tunnel and nerve damage in her right shoulder. She was also prescribed Wellbutrin and Lexapro, but stopped taking these during pregnancy because she was aware of the risks.

181. From the time she realized she was pregnant with S.B. in July 2016 until S.B.'s birth on April 8, 2017, Ms. Brizendine was prescribed and took at least 1,182 opioid pills, including OxyContin. Many of these pills were prescribed by Dr. Lawrence Peters as a part of his pain management practice. Upon information and belief, Dr. Peters was a "very high target M.D.," a class of doctors targeted by Purdue. Dr. Peters appeared in at least one McKinsey targeting list, in 2011, as a high-decile prescriber.

182. Ms. Brizendine was not an addict- her opioid prescription was for treatment of her pain, not to treat addiction. She was not prescribed and did not ingest Medication-Assisted Treatment drugs (MAT) prior to or during her pregnancy with S.B.

183. S.B. was born on April 8, 2017 at Norton Women's and Children's Hospital in Louisville, Kentucky. As a result of S.B.'s exposure to opioids in utero, she was diagnosed with NAS and spent her first three nights in the NICU. While in the NICU, she experienced tremors and hypertonia. S.B.'s ability to thrive has been severely if not permanently diminished due to in utero exposure to opioids.

184. As a further result of exposure to opioids in utero, S.B. suffered the following special injuries:

- Developmental disabilities
- Hearing impairment
- Gastrointestinal issues
- Serious vision problems
- Respiratory issues
- Attention problems
- Learning disability/Cognitive Delays
- Depression
- Social and behavioral difficulties
- 3 days in NICU

185. Had Ms. Brizendine known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

6. <u>April Hudak and H.S.</u>

186. April Hudak is the biological mother of H.S., who was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

187. Ms. Hudak was first prescribed opioids by her pain management physician in 2004 for chronic pain associated with fibromyalgia and rheumatoid arthritis. From 2009 through 2012, she was prescribed large quantities of OxyContin in combination with other opioids. In the 18-month period between December 2010 and June 2012, Ms. Hudak was prescribed and took over 3,700 opioid pills, including prescriptions by Dr. George Schakaraschwili, who attempted to taper down her dosage after she became pregnant, and Dr. Joel Schwartz, who continued prescribing her oxycodone through the pregnancy. Upon information and belief, Dr. Schwartz was targeted by McKinsey. As a result of her opioid prescriptions, she became dependent on opioids and eventually developed a condition known as opioid use disorder.

188. Ms. Hudak's opioid prescriptions were for treatment of her pain, not to treat addiction. She was not prescribed and did not ingest Medication-Assisted Treatment drugs (MAT) prior to or during her pregnancy with H.S.

189. During her pregnancy with H.S., Ms. Hudak was prescribed and consumed over 1,400 opioid pills. On June 6, 2012, she gave premature birth to H.S. in Aurora, CO at University of Colorado Hospital. As a result of her exposure to opioids in utero, H.S. was dependent on opioids at birth and spent the first thirteen days of her life in the hospital. In order to treat her opioid dependence, H.S. was administered methadone while in the NICU and after her discharge.

190. As a further result of exposure to opioids in utero, H.S. suffered the following special injuries:

- Growth/developmental delay

- 13 days in NICU

191. Had Ms. Hudak known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

7. <u>Timothy Lambert and M.L.</u>

192. Timothy Lambert is the biological father of M.L., who was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

193. M.L. was born on December 21, 2010 at Raleigh General Hospital in Beckley. M.L.'s biological mother died of a drug overdose in 2017. As a result of her opioid addiction, M.L. has been permanently deprived of their mother's comfort, care, and support.

194. Upon information and belief, M.L.'s biological mother was prescribed opioids both before and during her pregnancy with M.L. M.L.'s mother received prescriptions from Dr. Hassan "Nick" Jafary, who upon information and belief, was targeted by McKinsey. She also used opioids from the street prior to her pregnancy with M.L. She switched to Subutex during pregnancy. As a result, M.L. was exposed to opioids in utero and were born several weeks premature by emergency C-Section due to low amniotic fluid, and diagnosed with NAS at birth and treated for NOWS.

195. As a further result of exposure to opioids in utero, M.L. suffered the following special injuries:

- Learning difficulties
- Cognitive delays
- 26 days in NICU

8. <u>Jacqueline Ramirez and R.R.</u>

196. Jaqueline Ramirez is the biological mother of R.R, who was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

197. Ms. Ramirez was prescribed opioids, including Duragesic (manufactured by McKinsey client J&J) and Actiq (manufactured by McKinsey client McKesson), after a 2001 leg injury. Her doctor, Dr. Mat Wolfson, upon information and belief, was targeted by McKinsey.

198. On September 2, 2005, while still using Duragesic and Actiq, Ms. Ramirez gave birth to R.R. at Community Memorial Hospital in Ventura, California. Upon birth, R.R. experienced severe withdrawal symptoms as a consequence of fetal opioid exposure. R.R.'s medical records report incredibly high withdrawal symptoms including four consecutive scores of 14 on the Finnegan Scale. To treat him for opioid withdrawal syndrome, R.R. was administered medication assisted therapy, including methadone hydrochloride, phenobarbital, and hydrocortisone.

199. As a further result of exposure to opioids in utero, R.R. suffered the following special injuries:

- Arnold-Chiari brain malformation
- Sensory problems
- Digestive problems
- Hearing issues
- Vision issues
- Cognitive delays
- Social and behavioral problems
- 11 days in NICU

200. Had Ms. Ramirez known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

9. Julieann Valdez, J.V., and M.V.

201. Julieann Valdez is the biological mother of J.V. and M.V., who were born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

202. Ms. Valdez was first prescribed opioids in 2002 due to back and leg pain caused by a car accident and fibromyalgia, and continued to take OxyContin, Endocet and other opioid prescriptions through the pregnancies of J.V. and M.V. Dr. Steven Thackeray, who prescribed her opioids beginning in 2002, was targeted by McKinsey.

203. When she expressed concern to her doctors about continuing to take opioids during her pregnancy with J.V., PA Dr. Erin Toppins for pain management Dr. Sean Ponce told her it was safe and common. She continued to ask at nearly every appointment if she should continue to take opioids and was told the new baby may be a little shaky at first but wouldn't remember it and would be fine after a couple days. By contrast, Dr. Toppins warned her to stop taking her seizure and Xanax prescriptions during pregnancy, and the bottles of the seizure medicine had clear warnings regarding the risk to the fetus. Upon information and belief, Dr. Toppins and Dr. Ponce were targeted by McKinsey.

204. Her OB-GYN, Dr. Denise Jean Boudreaux-Nippert, was aware of her opioid prescriptions, once asking if Ms. Valdez planned to reduce her opioid dosage, but ultimately deferred to her pain management doctor and didn't mention it again. Dr. Boudreaux-Nippert was targeted by McKinsey.

205. Ms. Valdez remained on OxyContin and oxycodone throughout her pregnancy with J.V., resulting in fetal opioid exposure. J.V. was born premature in West Jordan, Utah at Jordan Valley Hospital on October 31, 2012, where he was diagnosed with NAS. J.V. also experienced respiratory distress, growth delays, and jaundice and failed to thrive. He remained in NICU for two weeks while he was treated with morphine and phenobarbital. Upon discharge, J.V. was sent home with phenobarbital. Throughout childhood, he has experienced numerous infections, including ear infections, throat infections, skin infections, and pneumonia. J.V. has also been diagnosed with oppositional defiance disorder, conduct disorder, and ADHD.

206. During her pregnancy with M.V., Ms. Valdez continued to be prescribed opioids, but she switched to methadone when she learned she was pregnant. Her OB-GYN, Dr. Gondy, was aware of her methadone treatment, but gave her no warning of the potential risks to the fetus. Dr. Gondy was targeted by McKinsey, appearing on at least one McKinsey targeting list, in 2017.

207. M.V. was born in Carson City, NV. At birth, M.V. was diagnosed with NAS and was treated for NOWS for nine days. She experienced tremors, convulsions, high-pitched cry, frequent sneezing, and constant diaper rash. M.V. is currently three years old, and Ms. Valdez has noticed some developmental delays in her.

208. As a result of exposure to opioids in utero, J.V. suffered the following special injuries:

- Behavioral problems including diagnosed oppositional defiance disorder and conduct disorder
- ADHD
- Serious vision problems
- Respiratory issues
- Delay in ability to walk
- Delay in ability to talk
- Depression
- Learning disability/Cognitive delays
- 14 days in NICU

209. As a result of exposure to opioids in utero, M.V. suffered the following special injuries:

- Gastrointestinal issues
- Respiratory problems
- 9 days in NICU

210. Had Ms. Valdez known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during her pregnancies.

Upon information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

10. <u>Cynthia Woolwine and E.G.W.</u>

211. Cynthia Woolwine is the biological mother of E.G.W., who was born dependent on opioids, and suffered additional special injuries as a result of exposure to opioids in utero.

212. Ms. Woolwine was a medic for around twenty years. During the course of her employment, she was regularly required to lift patients, and as a result, she developed carpal tunnel and compression fractures of the C4 and C5 vertebrae. She also dealt with fibromyalgia. Dr. Iraj Derakhshan prescribed her OxyContin and large quantities of other opioids, including Lortab, Endocet (manufactured by McKinsey client Endo), Percocet (manufactured by McKinsey client Endo), Nucynta (manufactured by McKinsey client J&J), and oxycodone, beginning in 2003. Ultimately she became opioid dependent. Dr. Derakhshan was targeted by McKinsey, appearing on McKinsey targeting lists in at least 2009. [redacted] Eventually Dr. Derakhshan would be forced to forfeit his license and was placed on probation for his excessive prescribing of opioids.

[redacted]

213. The prescriptions, written by Dr. Derakhshan which led to her addiction prior to her pregnancy with child E.G.W., were filled at Westside (Renegade) Pharmacy in Oceana, WV (pop. 1,407), which filled more opioid prescriptions than any other pharmacy in the county between 2006 and 2014, according to the Washington Post. Due to the abundance of illicit drugs in West Virginia, she later began buying pills from the street to satisfy her addiction.

214. Two months into her pregnancy with E.G.W., Ms. Woolwine was transitioned to Suboxone for medication assisted therapy by Dr. Hassan "Nick" Jafary (PCP). Dr. Jafary was targeted by McKinsey, appearing in at least one targeting list, in 2009. Ms. Woolwine continues to take Suboxone today.

215. Ms. Woolwine's OB-GYN, Dr. Todd Resley, was also targeted by McKinsey, appearing on at least one McKinsey target list, in 2001.

216. E.G.W. was born premature on November 14, 2012 by emergency C-section also at Raleigh General Hospital. She weighed less than five pounds at birth and exhibited many symptoms of NAS, including difficulty swallowing, muscle stiffness, and tremors. E.G.W. continues to have issues with her vision. She also experiences acid reflux problems, which cause her to have difficulty eating and gaining weight. She is currently nine years old but only around 40 pounds. E.G.W. was behind developmentally but has progressed closer to her grade level in recent years. However, E.G.W. still struggles with ADHD and has trouble focusing at school and in social settings.

217. As a result of exposure to opioids in utero, E.G.W. suffered the following special injuries:

- Growth/Developmental delays
- Serious vision problems
- ADHD
- Social/Behavioral difficulties

218. Had Ms. Woolwine known of the risk that these injuries can be caused by *in utero* opioid exposure, she would not have taken these opioid prescriptions during pregnancy. Upon

information and belief, if her prescribing doctors were aware of these risks, which were known to McKinsey but not disclosed, they either would have advised her of the risks in order to get her informed consent, or prescribed a non-opioid pain killer.

IX. FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

A. McKinsey's Anticompetitive Practices Drove Opioid Sales Through Collusion

219. McKinsey did what the pharmaceutical industry itself could not directly do—engage in anticompetitive practices through collusion. McKinsey had access to more data than any other actor in the Opioid Crisis: datasets on sales, discounts, and pricing that McKinsey had access to from its various pharma and regulatory client projects were shared and combined to form a McKinsey common database—including McKinsey's own Field Guide, as well as marketing and sales data—that McKinsey then manipulated, depending on the schemes it was working on at the time.

220. [redacted].[50] [redacted]

221. [redacted][51], [redacted][52], and [redacted][53] [redacted]

[50] One such example produced thus far in this litigation is MCK-MDL2996-0610565.
[51] An example based on the limited discovery produced thus far in this litigation is MCK-MDL2996-0097668.
[52] An example of this that has thus far produced in this litigation is MCK-MDL2996-0095748.
[53] An example of this produced in the discovery in this litigation thus far is MCK-MDL2996-0114459. [redacted]

[redacted][54] [redacted]

222. McKinsey is, quite literally, the sole repository on Earth of a collective knowledge bank of industry-wide tactics regarding the sales and marketing of opioids, and the outcomes thereof. This unique collection of knowledge and expertise made McKinsey a hub: even if any two given industry participants did not know what each other was doing, McKinsey knew exactly what *both* were doing because both were clients.

223. In short, one way in which McKinsey adds value for a client is by knowing what all of that client's competitors are doing. It possesses a greater body of knowledge about any given industry in which it advises multiple participants than any individual participant does itself.

224. McKinsey used an attachment to its Master Consulting Agreement, [redacted]

225. [redacted][55]

226. [redacted]**)…**

[redacted]

[54] An example of one such draft produced thus far in discovery in this litigation is MCK-MDL2996-2122059.

[redacted]

[55] MCK-MDL2996-0085896.

227. [redacted]

228. This [redacted] was integral to McKinsey's use of insights gained in boosting J&J's fentanyl sales to boost Purdue's OxyContin sales and then to use it experience boosting Purdue's OxyContin sales to boost Endo's Opana sales and then to use its experience boosting Opana sales to boost J&J's Nucynta sales.

229. McKinsey developed insights [redacted] to refine its physician targeting, geographic market segmentation, and drug rep messaging. Then McKinsey sequentially applied those lessons to drive sales of its clients' competitors.

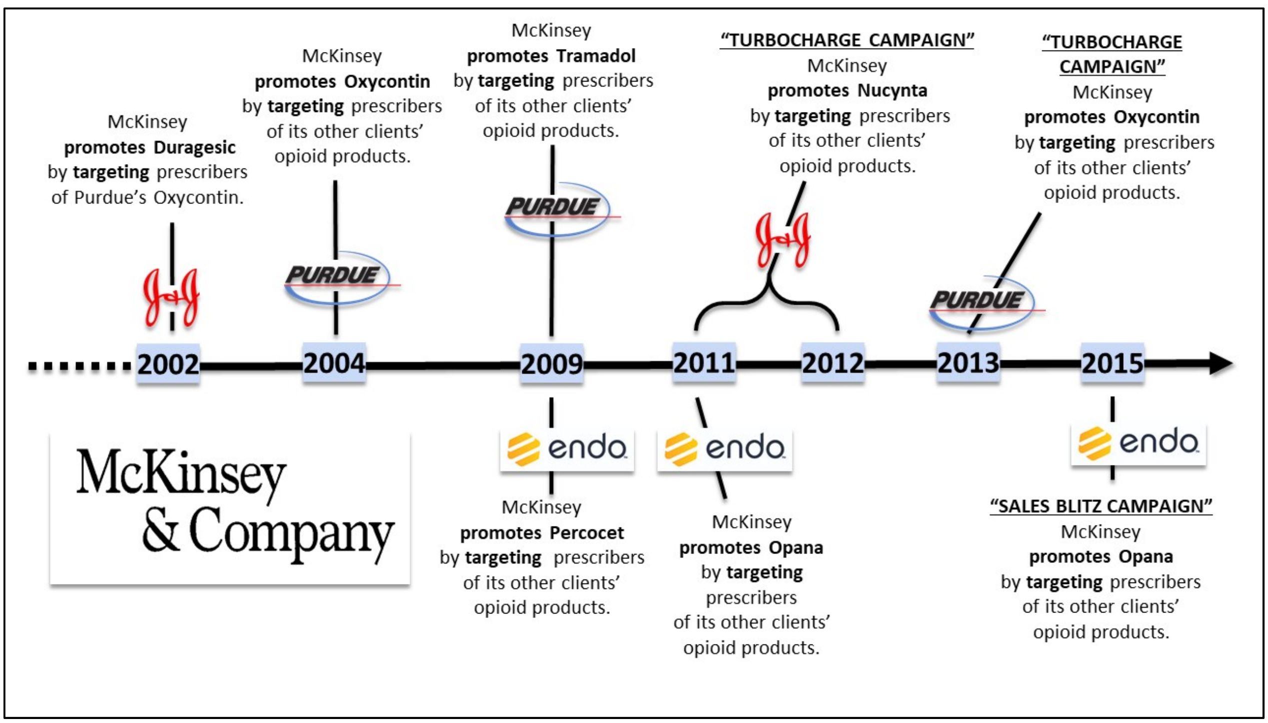
230. McKinsey designed, implemented, directed and oversaw sales of opioid for four manufacturers that had amassed massive market power.

231. For over 15 years, McKinsey colluded with opioid manufacturers including Purdue Pharma, Endo, Johnson & Johnson, and Mallinckrodt to knowingly sell their opioid products into the diversionary market in an effort to thwart the Controlled Substances Act. These four companies and their subsidiaries constituted over 57% of the opioid market by volume of pills sold and over 49% of the market by Morphine Milligram Equivalency between 2006 and 2014, according to the DEA's ARCOS database.

232. For at least seventeen years, McKinsey used insights garnered from wraparound market knowledge to time various competitors' increased sales efforts, either sequentially or simultaneously, to drive opioid sales into the diversionary market.

- 2002- McKinsey promoted J&J Duragesic by targeting the prescribers of Purdue's OxyContin.
- 2004- McKinsey promoted Purdue's OxyContin by targeting the competing opioid products manufactured by McKinsey's other opioid clients.
- 2009- McKinsey promoted Endo's Percocet by targeting competing opioid products manufactured by McKinsey's other opioid clients.

- 2009- McKinsey promoted Purdue's Tramadol by targeting competing opioid products manufactured by McKinsey's other opioid clients with a "Turbocharge" campaign.
- 2011- McKinsey promoted Endo's Opana by targeting competing opioid products manufactured by McKinsey's other opioid clients.
- 2011- McKinsey promoted J&J's Nucynta by targeting competing opioid products manufactured by McKinsey's other opioid clients with a "Turbocharge" campaign.
- 2012- McKinsey promoted J&J's Nucynta by targeting competing opioid products manufactured by McKinsey's other opioid clients with a "Turbocharge" campaign.
- 2013- McKinsey promotes Purdue's OxyContin by targeting competing opioid products manufactured by McKinsey's other opioid clients with a "Turbocharge" campaign.
- 2015- McKinsey promotes Endo's Opana by targeting competing opioid products manufactured by McKinsey's other opioid clients with a "Sales Blitz" campaign.



233. Each manufacturer's sales figures were that manufacturer's confidential information, but the insights gained by working with those sales figures belonged to McKinsey. For example, McKinsey was not technically selling Purdue's internal data to Endo, Mallinckrodt and J&J; McKinsey was using, for the benefit of Purdue's competitors, what it learned from

Purdue's confidential sale figures about how its design, implementation and oversight of sales efforts impacted Purdue's sales.

234. This put McKinsey in the proverbial cat-bird seat. It had the ability to drive the sales of opioids at will because it had the wraparound market knowledge to understand the tragic and illegal impact of increasing opioids sales without limit.

B. <u>Implementation: What Happens When the Client Says "Yes."</u>

235. McKinsey has previously argued that "the key weakness" of Plaintiffs' case is "that McKinsey is an advisor that does not control what its clients choose to do with the advice it provides." MTD (Doc. 462), at 8. McKinsey has argued that it is "implausible" that McKinsey "implemented its own recommendations." *Id.* at 7.

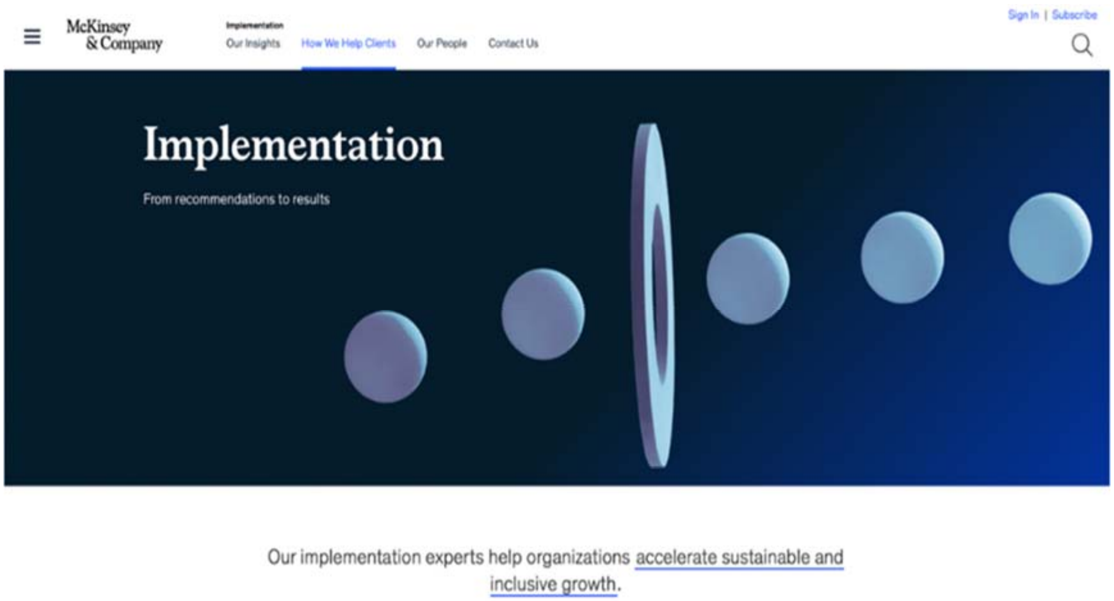
236. But, in McKinsey's own words, "McKinsey Implementation provides continuous, distinctive support to our clients to ensure they **achieve and sustain the full benefits of McKinsey's recommended changes**."[56] That language is plainly inconsistent with the notion that McKinsey's work stops with providing advice to its clients.

237. McKinsey has previously chastised Plaintiffs for using the word "implementation,"[57] but it is McKinsey's own language and practice that belies the notion that its work in implementation is "implausible."

[56] *See* https://www.mckinsey.com/careers/search-jobs/jobs/associateintern-implementation-15743.

[57] *See* MTD at 7-8 ("Plaintiffs merely repeat the work 'implement' over and over again without offering any factual allegation concerning how McKinsey 'implemented' its advice.").

238. For instance, here is the web page for McKinsey's Implementation practice group:[58]



239. "Implementation is tough, things don't always go to plan," McKinsey explains. "That's why we created McKinsey Implementation: to help our clients achieve the full results of their transformations… Our implementers have an extensive toolkit to deliver results."[59]

240. McKinsey also explains its implementation work in its recruiting efforts. For instance, McKinsey recently advertised a job on LinkedIn for a "Business Analyst" position in its Dallas office. "You'll work in teams of typically 3-5 consultants to identify, and *oftentimes implement*, potential solutions for a specific client problem or challenge."[60]

241. In Atlanta, McKinsey Implementation is hiring a "Procurement Consultant," who "will help clients to build the strategies, capabilities, systems and processes needed to deliver bottom line results and ensure those results are sustained… You will develop trust-based relationships with clients and be seen as a specialist in implementation and delivering results."[61]

[58] https://www.mckinsey.com/capabilities/implementation/how-we-help-clients.
[59] Video, https://www.mckinsey.com/capabilities/implementation/our-insights.
[60] *See* https://www.linkedin.com/jobs/search/?currentJobId=3286637821&keywords=mckinsey%20implementation (emphasis added).
[61] *See* https://www.linkedin.com/jobs/search/?currentJobId=2838241144&keywords=mckinsey%20implementation (emphasis added).

242. McKinsey is also hiring a "Process Improvement (Implementation) Associate in Denver: "You will help clients build capabilities in delivery and execution, both during an active project and continuing after our consultants have shared their recommendations."[62]

243. Currently, McKinsey is hiring for 326 positions relating to its "implementation" activities.[63] Implementation, by definition, means continuing to work with the client after the client has made a decision to adopt the advice. Because McKinsey remains in place to implement its advice post-adoption, McKinsey is therefore a principal actor in the actual doing of the tortious acts, not merely proposing them.

C. <u>McKinsey's Role in Pharmacovigilance and Drug Safety</u>

244. Through its role in pharmacovigilance, McKinsey aided and abetted massive and longstanding failures of pharmaceutical manufacturers to act vigilantly, encouraging them to fail to act upon new information from scientific findings on the dangers and side effects of opioids, as well as the cautionary language used by international opioid manufacturers clearly stating that opioid use is not recommended during pregnancy or is fully contraindicated during pregnancy.

245. Businesses in the pharmaceutical industry, such as McKinsey, are responsible for actively engaging in pharmacovigilance, which can be described as those activities relating to detecting, assessing, evaluating, and warning and preventing, adverse effects, side-effects, or any other medicine-related event. This is especially important with dangerous and addictive drugs such as opioids. The function of pharmacovigilance when it comes to opioid drugs is to vigilantly search for signals of problems with any opioid products, while the purpose behind acting vigilantly is to expedite reporting.

246. Pharmacovigilance includes the constant review of the literature reporting on its products and similar products, and it includes periodic safety update reports containing data and information concerning adverse event and other product safety related information.

247. In the area of pharmacovigilance, McKinsey aided and abetted massive and longstanding failures of pharmaceutical manufacturers to act vigilantly, encouraging them to fail

[62] *See* https://www.linkedin.com/jobs/search/?currentJobId=2679904353&keywords=mckinsey%20implementation (emphasis added).
[63] *See* https://www.mckinsey.com/careers/search-jobs?query=implementation.

to act upon new information regarding scientific findings on the dangers and side effects of opioids, as well as the publication by international opioid manufacturers of cautionary language stating that opioid use is not recommended during pregnancy or is contraindicated during pregnancy).

248. Here, with McKinsey's encouragement and oversight, opioid manufacturers failed to act vigilantly when they failed to act upon information concerning contraindication of opioids during pregnancy, as seen in the form of internal entries maintained by the manufacturer defendants, as well as in the form of authoritative determinations and explicit warnings in summary of product characteristics.

249. McKinsey is liable for consciously disregarding information both material and relevant to the use and efficacy of opioids with respect to special populations that include pregnant women and their unborn child.

250. Upon information and belief, McKinsey engaged in pharmacovigilance advising for Purdue and other opioid manufacturers, kept abreast of the latest scientific information for inclusion in updated internal documents and applications to regulators, and advised Purdue and other manufacturers on the drafting and editing of these internal safety documents and submissions to the FDA in a manner in which to best obtain marketing approval by those regulatory agencies.

251. U.S. pharmaceutical manufacturers both staff and maintain elaborate and highly sophisticated document management systems cataloging, for example, information and data concerning pre-clinical and clinical research; investigational new drug applications ("INDA"); new drug applications ("NDA"); abbreviated new drug applications ("ANDA"); supplemental drug applications ("SDA"); literature reviews; periodic safety update reports ("PSUR") and periodic benefit-risk evaluation reports ("PBRER"); summary of product characteristics ("SmPC") company core data sheets ("CCDS") and similar. Outside the U.S., the counterpart to the CCDS is commonly described as the Development Core Safety Information ("DCSI") that, in turn, evolves into the company core safety information ("CCSI").

252. In these documents, produced under the direction of McKinsey, language in submissions to foreign regulatory bodies more clearly warn against use during pregnancy, and in fact contraindicate (absolutely forbid) use of opioid drugs in pregnancy. These warnings were not duplicated in their corresponding US materials until much later—it was not until 2014 that Purdue's OxyContin carried a Black Box Warning strongly against use during pregnancy. Prior to this, warnings were much softer, falsely claiming that scientific evidence was insufficient to fully warn against such use. This Black Box Warning was only included upon the publication of the Broussard study in 2010, which overwhelmingly showed a link between opioid use in pregnancy and dangers to the developing fetus.

253. In practical terms, while the Defendants' marketing materials in the United Kingdom, Poland, Germany, Australia, and New Zealand, and elsewhere globally—e.g., patient medication guides and material safety data sheets—explicitly warned prescribers and users of the profound risks of fetal opioid exposure and birth defects, the same opioid manufacturer clients of McKinsey chose not to warn users and prescribers within the United States of the same risks.

254. McKinsey's strategic role in orchestrating cooperation among opioid manufacturers, distributors, and retailers makes McKinsey liable for aiding and abetting and engaging in a conspiracy to withhold from the U.S. marketplace information that is both material and relevant to pregnant women and women of childbearing ages regarding their bodies and the health and safety of their fetuses and unborn children.

255. One of McKinsey's first engagements [redacted] In this case specifically the impact of McKinsey's substantial assistance and encouragement has been to keep the plain language explanation of risk of birth defects away from expectant mothers and their doctors.

[redacted]

[redacted]

[redacted]

256. Upon information and belief, McKinsey advised opioid manufacturers to downplay or fail to mention in applications to the U.S. FDA and domestic regulators the readily scientific studies which formed the basis of these foreign warnings against use during pregnancy and contradictions against use during pregnancy and nursing. McKinsey knew it was withholding from the FDA and the public valuable safety information that could have avoided the birth of thousands of children suffering from congenital defects and NAS related to their mothers' use of

opioids during pregnancy, but McKinsey prioritized profits over the health of pregnant women and newborns.

D. McKinsey's Work with Johnson & Johnson

1. McKinsey's Early Work with Johnson & Johnson

257. McKinsey worked with Johnson & Johnson, whose role overseeing and contributing to the opioid crisis has been exhaustively detailed in other complaints. *See, e.g., City & County of San Francisco v. Purdue Pharma L.P.*, N.D. Cal. No. 18-2591, Doc. 128 (Mar. 13, 2020). Johnson & Johnson occupied multiple roles within the opioids industry. Through its subsidiary, Janssen Pharmaceuticals ("Janssen"), it marketed and sold branded opioid products, including Duragesic (a transdermal fentanyl patch) and Nucynta (tramadol tablets and oral solution). Through its Noramco and Tasmanian Alkaloids subsidiaries, Johnson & Johnson farmed the poppy plant in New Zealand and created the precursor chemical and raw materials necessary to manufacture all opioids. Noramco and Tasmanian Alkaloids sold these raw materials to the other opioid manufacturers: Purdue, Endo, Mallinckrodt, and others. Johnson & Johnson was the origin point in the entire opioids supply chain.

258. Just like McKinsey's relationships with Purdue, Endo, and the others, McKinsey's opioid-related work for Johnson & Johnson spanned decades.

259. Just as Endo was led by former partner McKinsey partner Rajiv de Silva, Johnson & Johnson similarly relied on McKinsey as a pipeline for its own management timber. As described above, McKinsey alumni tend to move on to positions with McKinsey clients. Janssen's current Director of Customer Marketing & Value Based Care was hired from McKinsey's PMP group. The relationship flows both ways: Janssen's former Vice President of Sales and Marketing for Janssen Pharmaceuticals is currently a McKinsey partner. Moreover, Ian Davis has been an independent director since 2010 and currently sits on the Audit and Regulatory Compliance committees of Johnson & Johnson's board. Previously, he was a Senior Partner at McKinsey, "having served as Chairman and Worldwide Managing Director from 2003 until 2009."[64]

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[64] https://www.jnj.com/leadership/ian-e-l-davis.

260. Kevin Sneader, until recently McKinsey's global managing partner, and one of Davis' successors, described Davis as a "mentor" who was the managing partner of McKinsey's London office when Sneader was working there and "worked on one of his teams."[65] Given Frazier's presence on the board, Johnson & Johnson was obviously an important account for McKinsey. At present, it is not known which McKinsey partner(s) was the Director(s) of Client Services for the Johnson & Johnson account.

261. What is known, however, is that McKinsey [redacted][66] On July 6, 2011, Ghatak attended an internal McKinsey call with the consultants working on the Johnson & Johnson account to discuss the "J&J Nucynta sales force disruption."[67] The same day, Laura Moran, who like Ghatak worked both the Purdue and Endo accounts, also provided internal advice regarding Nucynta to her McKinsey partner Gerti Pellumbi, who was leading Nucynta sales efforts for the Johnson & Johnson account, and engagement manager Bryan Reinholt, who was with Pellumbi on the Johnson & Johnson account. [68] Martin Elling, one of the lead McKinsey partners on the Purdue account alongside Ghatak, attended internal McKinsey calls on March 25, 2010,[69] and again on May 27, 2011 to discuss McKinsey's work for Johnson & Johnson's Nucynta.[70] Then, on December 13, 2011, Elling attended a meeting with Johnson & Johnson personnel regarding "acceleration opportunities."[71] Aamir Malik attended the meeting with Elling, and, naturally, also worked on the Endo account.[72] Malik and Ghatak had an internal

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[65] *See* Interview with Kevin Sneader, Harvard Project for Asian & International Relations, January 31, 2021, *available at* https://www.youtube.com/watch?v=qed53EGG8kU
[66] JAN-NH-00167575.
[67] MCK-MDL2996-0222833.
[68] MCK-MDL2996-0419348.
[69] MCK-MDL-2996-0256186.
[70] MCK-MDL-2996-0255907.
[71] MCK-MDL-2996-0255926.
[72] *Id.*; *see also* MCK-MDL-2996-0348536 (Example of Malik's work on Endo account).

McKinsey meeting amongst themselves regarding the "Nucynta Kickoff" at Johnson & Johnson six months prior, on June 3, 2011.[73]

2. Noramco and the Worldwide Narcotics Franchise

262. Janssen was not the only Johnson & Johnson unit [redacted], and Janssen was not Johnson & Johnson's only division involved in the narcotics trade. McKinsey substantially assisted and encouraged Johnson & Johnson in its creation of a worldwide narcotics trade.

263. Opioids—all of them—are derivatives of opium, which is derived from the poppy plant. In order to sell opioids, someone needs to farm the opium poppy and process the harvest into the raw materials necessary for opioid manufacturers—all of them—to make their products.

264. Johnson & Johnson was that farmer. It owned Noramco and Tasmanian Alkaloids, which grew poppies in New Zealand and sold the raw ingredients for opioids to practically all manufacturers.

265. On August 19, 2009, McKinsey's [redacted][74]

266. [redacted][75]

[73] MCK-MDL-2996-0261694.
[74] NORAMCO_TX_01136410.
[75] NORAMCO_TX_01136411, slide 4.

[redacted]

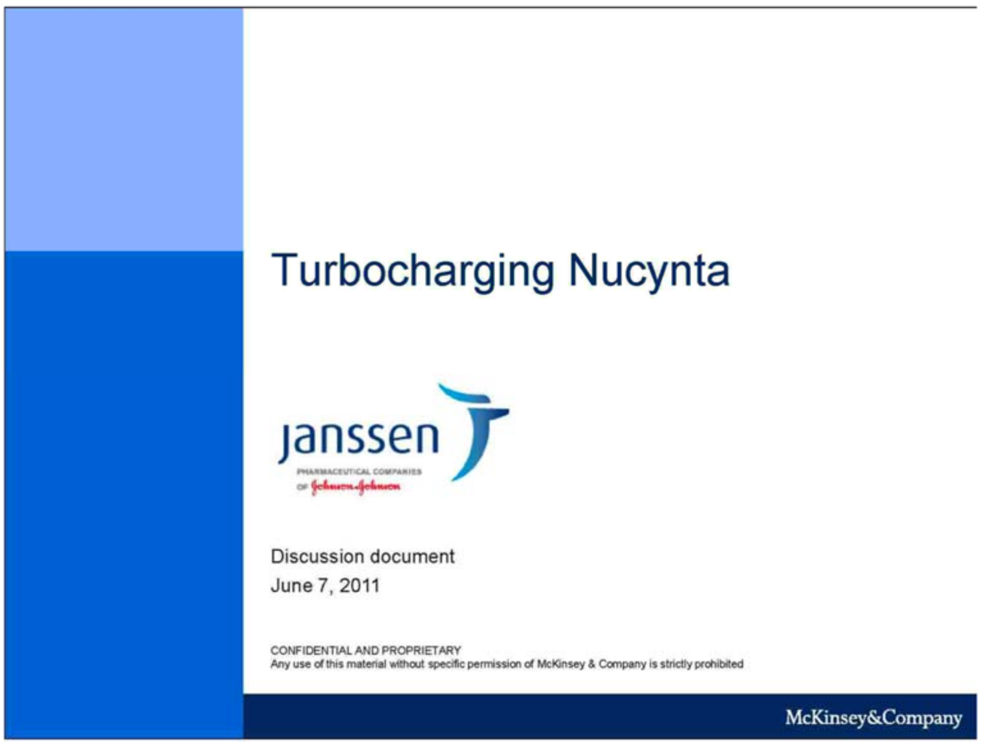
267. Seven years later, in 2016, Johnson & Johnson exited the business by selling Noramco and Tasmanian Alkaloids to SK Capital, a private equity firm focused on the pharmaceuticals business, for approximately $800 million.[76] [redacted] Not only was McKinsey's advice invaluable to Johnson & Johnson, the perspective McKinsey gained of the overall opioid market from advising the principal upstream supplier to the entire industry would be invaluable in to its own work with its other opioid manufacturer clients.

268. McKinsey substantially assisted J&J in the formation, maintenance and ultimate sale of its World Wide Narcotics Franchise consisting of Janssen, Noramco, and Tasmanian Alkaloids (and perhaps other entities unknown as yet). McKinsey's assistance and encouragement substantially contributed to the public nuisance created by its opioid clients.

[76] Gareth Macdonald, "US Investor buys J&J's opiate API business and announces restructuring," *Outsourcing Pharma*, July 20, 2016, *available at*: https://www.outsourcing-pharma.com/Article/2016/07/21/US-investor-buys-J-J-s-opiate-API-business-and-announces-restructuring.

3. Turbocharging Nucynta

269. McKinsey's infamous Project Turbocharge to boost OxyContin sales at Purdue in 2013 and 2014—the same project detailed in Purdue's 2020 guilty plea with the Department of Justice—was not McKinsey's first experience turbocharging opioid sales. Before OxyContin, there was Nucynta:[77]



270. Nucynta was Janssen's branded tapentadol product. Tapentadol is generally regarded as a moderately strong opioid. Nucynta was first approved as a Schedule II controlled opioid agonist tablet and oral solution in 2008, and indicated for "relief of moderate to severe acute pain in patients 18 years of age or older." In 2011, Janssen obtained approval for a long-acting version Nucynta ER, which was indicated for "management of moderate to sever chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults."

271. McKinsey is a repeat opioid sales turbocharger. McKinsey's efforts to turbocharge Nucynta sales resembled those it later deployed in more robust form at Purdue a few years later.

[77] MCK-MDL-2996-0135636.

For example, "physician prescribing habits," and "switching behavior," were external factors McKinsey identified as key issues "impacting future Nucynta growth." Understanding these issues at a granular level would be crucial, including "What is physician/market awareness of Nucynta ER? By physician segment?"[78] These same factors drove McKinsey's later work turbocharging OxyContin.

272. Along the way, McKinsey [redacted][79]

273. Despite this ambivalence about tamper-resistance, in a status update on June 23, 2011, McKinsey informed Janssen that its "initial physician interview findings" indicate Nucynta ER has "lower addictive/abuse potential and side-effect profile as key differentiators vs. OxyContin ER."[80]

274. As part of the turbocharge process, [redacted][81]

275. By 2014, Janssen was began exploring the sale of Nucynta, and McKinsey was involved in the process. Incredibly, [redacted][82] Purdue ultimately did not purchase Nucynta. Instead, in 2015, Johnson & Johnson's

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[78] MCK-MDL-2996-0135636.
[79] JAN-MS-00322271.
[80] MCK-MDL-2996-0009526, at 0009529.
[81] JAN-MS-02272779.
[82] PPLPC023000661013 [redacted].).

Janssen unit sold its Nucynta rights to another manufacturer, Depomed Inc., for just over one billion dollars.[83]

276. The year prior, Nucynta accounted for $172 million in annual sales for Janssen. Janssen described the Nucynta sale to Depomed as "a strategic decision designed to focus efforts on growth efforts."[84] Depomed, for its part, saw the Nucynta acquisition as a transformational opportunity to position itself as "a pain and neurology-focused specialty pharmaceutical company."[85]

277. When Depomed bought Nucynta, [redacted]

[redacted][86]

E. McKinsey Provided Purdue Substantial Assistance in Committing Crimes

1. Purdue 2007 Guilty Plea

278. McKinsey, utilizing its wraparound knowledge, aided, abetted, and facilitated Purdue's illegal acts, resulting in an opioid crisis of the unborn from at least as early as 2004 until the 2019.

279. Purdue has acknowledged these criminal violations in two separate criminal guilty pleas - first in 2007, and more recently in 2020.

280. Purdue's guilty plea put McKinsey on notice of Purdue's misconduct. By that time, McKinsey had access to public information indicating that OxyContin and other opioids

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[83] *See* https://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html

[84] Josh Beckerman, "DepoMed to Buy U.S. Rights to Nucynta From J&J Unit," *Wall Street Journal*, January 16, 2015, *available at*: https://www.wsj.com/articles/depomed-to-buy-u-s-rights-to-nucynta-from-j-j-unit-1421357503

[85] *Id.*

[86] DEPO-CDI-00071072 (emphasis added).

pose significant risk of addiction and misuse, with a myriad of public health effects, including the creation of an opioid crisis among the unborn.

281. McKinsey was also aware of the risks of OxyContin based on its wrap around knowledge of the pharmaceutical industry landscape and specialization in public health consulting.

282. In Purdue's 2007 guilty plea, the company plead guilty to charges totaling $634,515,475 for defrauding government regulators as well as doctors and the medical community through false claims that OxyContin was less addictive, less subject to diversion, and presented less side effects than any other treatment for chronic pain. *See* Purdue 2007 Guilty Plea.

283. In 2007 United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty plea of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the misbranding of OxyContin. Brownlee stated,

> Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain medications on the market.

284. As a result of the 2007 guilty plea, the Sacklers made the strategic decision to distance the family from Purdue, which was regarded, in the words of Richard Sackler, as an increasingly dangerous "concentration of risk" for Purdue's owners. Ten days after the guilty plea was announced, David Sackler wrote to his father, Richard Sackler, and uncle, Jonathan Sackler, describing precisely what that "risk" was: legal liability for selling OxyContin. In response to Jonathan stating that "there is no basis to sue 'the family,'" David replied:

Message

From: David Sackler [redacted]
Sent: 5/17/2007 11:08:08 PM
To: 'Sackler, Jonathan' [redacted] Sackler, Dr Richard [redacted]
CC: Ives, Stephen A. [redacted]
Subject: RE: Idea
Attachments: image001.jpg

Well I hope you're right, and under logical circumstances I'd agree with you, but we're living in America. This is the land of the free and the home of the blameless. We will be sued. Read the op-ed stuff in these local papers and ask yourself how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten us.

285. Notably, under the terms of Paragraph II.C.1(b) of the Corporate Integrity Agreement, McKinsey, as a contractor to Purdue performing sales and marketing functions for the company, was itself a "Covered Person" subject to the strictures of the Agreement.[87]

286. McKinsey, knowing of their client's criminal plea and through their wrap around knowledge, the worsening opioid crisis, continued to work with Purdue on increasing sales by more efficiently targeting health care providers and unscrupulously focusing on the highest decile prescribers of OxyContin.

2. Purdue Tasks McKinsey with Boosting Opioid Sales in Light of the Guilty Plea and Corporate Integrity Agreement.

287. After the settlement the Sacklers faced a problem: the need to grow OxyContin sales as dramatically as possible so as to make Purdue an attractive acquisition target or borrower, while at the same time appearing to comply with the Corporate Integrity Agreement. As one Purdue executive stated of Purdue's attitude toward the Corporate Integrity Agreement: "They did not listen to their critics and insisted they had just a few isolated problems. After the settlement, they didn't change—the way the sales force was managed and incentivized, everything stayed the same."[88]

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[87] The relevant language in the Corporate Integrity Agreement provides: "'Covered Persons' includes . . . all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions . . . on behalf of Purdue." PDD1712900096.

[88] David Crow, *How Purdue's 'one-two' punch fuelled the market for* opioids, Financial Times, Sept. 9, 2018, *available at:* https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

288. Purdue and the Sacklers were well aware of the constraints posed by the Agreement. Indeed, during a May 20, 2009 Executive Committee Meeting, the discussion led to whether Purdue should have a single sales force marketing all Purdue products, including OxyContin, or instead to "create a separate Sales Force for Intermezzo (a sleeping pill) that would be comprised of approximately 300 representatives." John Stewart, Purdue's then-CEO, saw an opportunity, and asked if the Corporate Integrity Agreement would apply if Purdue were to launch Intermezzo and another Purdue product, Ryzolt (a branded version of Tramadol, another narcotic painkiller), using the separate sales force. Might the new drug launch fall outside of the Corporate Integrity Agreement, he asked?[89]

289. It would not, he was told by Bert Weinstein, Purdue's Vice President of Compliance.[90]

290. Given the tension between compliance with the Corporate Integrity Agreement and the desire to sell more OxyContin, Purdue needed help.

291. Ethan Rasiel, a former McKinsey consultant, has described the typical way McKinsey begins working with a client: "An organization has a problem that they cannot solve with their internal resources. That's the most classic way that McKinsey is brought in."[91]

292. Such was the case with Purdue. Because it did not have the requisite expertise to address the problems posed by the Corporate Integrity Agreement internally, Purdue expanded on its already-existing relationship with McKinsey to devise a sales and marketing strategy to increase opioid sales despite the Corporate Integrity Agreement and growing concern about the "concentration of risk" that Purdue's business of selling opioids posed to its owners.

293. McKinsey's task was to thread the needle: to increase OxyContin sales despite the strictures imposed by the five-year Corporate Integrity Agreement. This McKinsey did, turbocharging[92] the sales of a drug it knew fully well was addictive and deadly, while purporting to respect to the Corporate Integrity Agreement.

[89] PPLPC012000226606, Purdue Pharma Executive Committee Meeting Notes and Actions, May 20, 2009, Pg. 2.
[90] *Id.*
[91] *How McKinsey Became One of the Most Powerful Companies in the World*, CNBC, June 6, 2019 *available at:* https://www.youtube.com/watch?v=BBmmMj_maII.
[92] If the description is overbearing, note that it is McKinsey's own, as described below.

294. In short, Purdue would pay money to McKinsey in exchange for McKinsey enabling the company to sell as much OxyContin as conceivably possible so that the Sacklers could obtain cash to diversify their investment holdings away from Purdue, and keep their money safe from the reach of court judgments, fines, and penalties they feared.

295. Consistent with their plan to dissociate themselves from the company, the Sacklers appointed Mr. Stewart as the CEO of Purdue in 2007. The Sacklers viewed Stewart as someone loyal to the family. He had previously worked for a division of Purdue in Canada. Stewart's job was to assist the Sacklers with the divestiture or eventual orderly wind-down of Purdue. Stewart was paid more than $25 million for his services to Purdue from 2007 through 2013.

296. Purdue's Executive Committee discussed Stewart's concerns regarding the constraints posed by the Corporate Integrity Agreement on May 20, 2009. Within weeks, McKinsey was working with Purdue to devise and implement new marketing strategies for OxyContin.

297. Stewart, as CEO, was in charge of the relationship with McKinsey. He controlled workflow to and from McKinsey and required his personal approval for any work orders with McKinsey.

298. In addition, Purdue's Vice President of Corporate Compliance, "responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in the [Corporate Integrity Agreement]," reported directly to Stewart.[93]

299. Throughout their relationship, McKinsey routinely obtained information from, advised, communicated with, and ultimately worked for the Purdue board of directors, controlled by the Sackler family.

300. McKinsey would also work in granular detail with the Purdue sales and marketing staff, led during the relevant period by Russell Gasdia, Vice President of Sales and Marketing.

301. From as early as June 2009 and continuing at least through July 14, 2014, Purdue routinely relied upon McKinsey to orchestrate its sales and marketing strategy for OxyContin.

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[93] PDD1712900096.

The relationship was characterized by ongoing interactions between teams from McKinsey and Purdue regarding not only the *creation* of an OxyContin sales strategy, but also its *implementation*. McKinsey was a real presence at Purdue. "A team of McKinsey analysts went in-house, camping out in a conference room at Purdue headquarters."[94]

a. <u>McKinsey Triples OxyContin Sales After Guilty Plea</u>

302. Within five years of the guilty plea, OxyContin sales would triple. McKinsey is responsible for the strategy that accomplished this. It presented specific plans to Purdue, which Purdue adopted and spent hundreds of millions of dollars implementing. The result: a final spasm of OxyContin sales before the inevitable decline of the drug.[95]

303. The Purdue McKinsey collaboration was a spectacular success. Between the 2008 and 2016, Purdue distributed in excess of $4 billion to the Sackler family, with $877 million distributed in 2010 alone.

304. These distributions would not have been possible without McKinsey's work dramatically increasing OxyContin sales.

305. McKinsey's contributions to Purdue's growth after 2007 are remarkable. OxyContin sales should have naturally declined; the Department of Justice identified OxyContin sales that were illegitimate because of Purdue's conduct, and the Inspector General of the Department of Health and Human Services entered into a Corporate Integrity Agreement whereby Purdue was monitored to assure that those sales did not continue.

306. In 2007, the year of Purdue's guilty plea, net sales of OxyContin totaled approximately $1 billion.[96]

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[94] Patrick Radden Keefe, *Empire of Pain* 302 (2021). In September, McKinsey named Mr. Keefe's history of the Sackler family and Purdue and the opioid crisis to its 2021 shortlist for "Business Book of the Year." *See https://www.mckinsey.com/about-us/new-at-mckinsey-blog/for-your-reading-list-the-2021-business-book-of-the-year-shortlist*.

[95] On February 10, 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.

[96] *See* David Crow, *How Purdue's 'one-two' punch fueled the market for opioids*, Financial Times, Sept. 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

307. The guilty plea "did little to stem Purdue's blistering growth rate." In fact, by 2010, after McKinsey was advising Purdue on how to maximize sales, OxyContin sales exceeded $3 billion: a *tripling* of revenue from OxyContin sales.[97]

308. Under McKinsey's guidance, OxyContin sales would reach their all-time peak in 2013, the year McKinsey proposed, and Purdue adopted, Project Turbocharge.[98] That OxyContin sales peaked in 2013 is especially notable, given that *overall* opioid prescriptions had *already peaked* three years earlier, in 2010.[99] McKinsey's efforts added a final boost to OxyContin sales before the eventual unraveling, and Purdue's decision, in the end, to cease marketing the drug.

309. Project Turbocharge was a continuing success. [redacted][100] and Chief Financial Officer Edward Mahoney reported to the Purdue board that the effort "has resulted in significant improvement." [redacted].[101]

310. McKinsey was paid handsomely: it received more than [redacted] for its work for Purdue from 2008 to 2013 alone.[102] In pursuit of these profits, McKinsey continued to help Purdue grow opioid sales even after Purdue reached a 2015 Assurance of Discontinuance with New York arising out of an investigation concerning its Abuse and Diversion Detection program and media coverage highlighted its lack of attention to diversion control. McKinsey's own work elsewhere identified "reducing prescribing" as among the efforts to combat the opioid epidemic and also showed that opioid prescribers were frequently writing prescription for patients with known risks of abuse. Still, McKinsey continued to work to help opioid manufacturers increase opioid sales, including through Purdue's deceptive marketing campaign.

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[97] *Id.*

[98] Phil McCausland and Tracy Connor, *OxyContin maker Purdue to stop promoting opioids in light of epidemic*, NBC News, Feb. 10, 2018, *available at:* https://www.nbcnews.com/storyline/americas-heroin-epidemic/OxyContin-maker-purdue-stop-promoting-opioids-light-epidemic-n846726.

[99] Gery P. Guy Jr, *at al.*, *Vital Signs: Changes in Opioid Prescribing Patterns in the United States, 2006-2015*, Centers for Disease Control and Prevention, July 7, 29017, *available at:* https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.

[100] PPLPC037000159028.

[101] PPLPC014000263961.

[102] PPLPC029000547371.

311. By 2014, according to Purdue, there were 5.4 million OxyContin prescriptions written, 80% for twelve-hour dosing. Of those prescriptions, more than half were for doses greater than sixty milligrams per day.

312. McKinsey advised Purdue on expanding OxyContin to Asian markets in 2013, especially China and South Korea. McKinsey viewed these markets as presenting untapped potential that could yield massive profits through the application of the same ruthless sales tactics utilized domestically for OxyContin, including high decile prescriber targeting.[103] Even though Purdue was under heightened scrutiny in the United States in 2013, affecting sales of the drug domestically, Richard Sackler and McKinsey agreed that China, South Korea and other Asian markets presented great opportunities to turbocharge opioid sales and profits.

313. The Sackler family has withdrawn over $10 billion from Purdue since 2008, including $1.7 billion in 2009 alone. These distributions were made possible by McKinsey's services and came at the expense of a deepening national opioid crisis.

b. Purdue's 2020 Guilty Plea

314. In the years after the 2007 guilty plea, McKinsey, through its high-powered consultants, continued to aid and abet Purdue's unethical and illegal acts. McKinsey worked tirelessly to ensure that Purdue, now under increased public and government scrutiny, continued to profit from the sale of addictive opioid drugs.

315. McKinsey's strategy of directing Purdue's sales team target the highest prescribing "pill mill" doctors was successful in increasing the number of opioid prescriptions, and ultimately resulted in an opioid crisis of the unborn, as thousands of women of child bearing age fell victim to addiction.

316. McKinsey's advice to defraud the medical community directly aided and abetted Purdue's criminal activities. McKinsey knowingly and willingly helped facilitate Purdue's illegal schemes to increase opioid addiction. Purdue would soon plead guilty to criminal charges once again, this time stemming directly from McKinsey's advice.

[103] MCK-MDL2996-0222999- R Sackler-Rob Rosiello China Email.

317. Purdue's 2020 guilty plea repeatedly refers to "a consulting company" which advised them to continue breaking the law while avoiding the scrutiny of regulators and doctors that were increasingly more suspicious of the safety of opioid drugs.

318. Based upon publicly available evidence, it is clear that "the Consulting Company" in question who provided the advice which makes the basis of the 2020 criminal guilty plea is none other than McKinsey & Co.

319. In the 2020 guilty plea, when first hired by Purdue in the mid-2000s, the "consulting company" attributed Purdue's slowing sales to new "safeguards against medically unnecessary prescriptions", also noting in 2013 that "[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk."

320. According to Purdue's 2020 guilty plea, the "Consulting Company" advised Purdue to implement a strategy of 'Turbocharging the Sales Engine' through the targeting of the highest deciles of OxyContin prescribing doctors in order to exponentially increase prescriptions and thereby sales of OxyContin.

321. The 2020 guilty plea notes that this strategy was "overseen by the consulting company and some of Purdue's top executives." *See* Purdue 2020 Guilty Plea at 111.

322. Upon the advice of and with the oversight of the consulting company, McKinsey & Co., Purdue's sales team targeted the highest decile, "extreme high volume" OxyContin prescribing doctors. This strategy was successful in increasing OxyContin prescriptions, thereby also leading to more opioid addiction among women of childbearing age and increased cases of neonatal abstinence syndrome, developmental delays, and birth defects.

323. McKinsey's consulting advice and expertise was integral to accomplish Purdue's goals of criminally increasing OxyContin and opioid prescriptions. This led directly to thousands of women of childbearing age to become addicted to opioids, and their unborn children to suffer.

F. <u>McKinsey's Work with Endo</u>

324. While McKinsey was working for Purdue, McKinsey was also working for Endo Pharmaceuticals. Arnab Ghatak was a principal McKinsey partner on both accounts at the same

time.[104] There was additional overlap between the McKinsey teams staffed to Purdue and Endo, including McKinsey partners Nicholas Mills and Laura Moran. After all, these particular consultants had granular expertise in the specific subject-matter relevant to these opioid manufacturers. That subject-matter expertise is a compelling reason why McKinsey is hired in the first place. McKinsey advised both Endo and Purdue how to maximize the sales or their branded opioid products—Belbuca (Buprenorphine), Butrans (Buprenorphine), Opana (Oxymorphone), and OxyContin (Oxycodone) —all at once.

325. In 2006, Endo launched its own branded oxymorphone products, Opana and Opana ER.[105] With the launch of Opana, Endo decided it was time for history to repeat itself. After Opana's approval, orchestrated by McKinsey after Endo failed to achieve approval on its own, Endo solidified its position as a pain specialist among manufacturers.

326. By 2012, opioid sales accounted for approximately $403 million of Endo's $3 billion in revenue, more than 10%. From 2010 to 2013, total Opana ER revenue alone exceeded $1.1 billion.

1. <u>Opana's Launch</u>

327. McKinsey's relationship with Endo began as early as in 2006, the same year as the Opana launch.

328. McKinsey's earliest known work with Endo concerned the launch of Opana in Europe, but its relationship with Endo would expand to encompass all aspects of Endo's business, including corporate organization and resource allocation, the launch of a new branded Buprenorphine product, and sales force optimization efforts for Endo's branded and generic opioid products.

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[104] Ghatak's familiarity with both Endo and Purdue is perhaps one reason why, on April 3, 2014, Ghatak was placed in charge of analyzing a proposed *partnership* between Purdue and Endo to sell opioids. Lauran Moran described the "partnership workstream" that McKinsey was then performing for Purdue to identify ways for Purdue to obtain near-term growth. She stated that Purdue and McKinsey "agreed the partnerships workstream should include the top 3 potential partners (Valeant, Endo and Pfizer for now). And for each what assets each partner would bring and what growth (most importantly) would the deal bring. Arnie [Ghatak] and Phil to work out Endo and Valeant, John G and Raul to do Pfizer tomo." MCK-MDL2996-0421790.

[105] https://www.endo.com/about-us/history#fragment-15.

329. In 2007, McKinsey was shaping overall corporate strategy at Endo. In a presentation to Endo's board of directors in May of that year [redacted][106]

330. McKinsey's partnership with Endo would last more than a decade, and, like its relationship with Purdue, is an exemplary example of the transformational relationship in action.

331. In some ways, the McKinsey's relationship with Endo was even more tightknit and companionable than with Purdue. For instance, no one at Purdue previously worked for McKinsey. In early 2013, Rajiv de Silva, previously a leader of McKinsey's PMP group, was appointed CEO of Endo. At Endo, McKinsey was now advising an old friend, one of its previous senior partners.[107]

332. As de Silva himself explained, [redacted][108]

333. Under de Silva, Endo relied more heavily on McKinsey than ever before. McKinsey consultants interacted directly and often *exclusively* with de Silva. McKinsey was so close to the Endo CEO that it could intervene in direct reporting from one of de Silva's deputies.[109] It is as if McKinsey had insinuated itself as a shadow layer of bureaucracy within Endo.

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[106] ENDO-OPIOID_MDL-02899510.

[107] *See* "Rajiv De Silva Named President and CEO of Endo Health Solutions," Press Release dated February 25, 2013, *available at*: https://investor.endo.com/news-releases/news-release-details/rajiv-de-silva-named-president-and-ceo-endo-health-solutions ("Earlier in his career, he was a Principal at McKinsey & Company, where he served as a member of the partnership group that led the global Pharmaceuticals and Medical Products practice.")

[108] ENDO-OPIOID-DEPMAT-000047877 at pg. 320:22 – 321:3.

[109] *See* MCK-MDL2996-0405502 (Email from Ghatak to de Silva, stating that it "would be great for you to push Blaine and Bob [both Endo employees] on why there are no slides showing the metrics on field call attainment . . . there was an explicit agreement to track them. Setting the expectation that you want them included would really help").

334. McKinsey maintained weekly performance review meetings with de Silva and senior Endo management. In these meetings, granular weekly sales data was reviewed for each of Endo's branded products, including Opana.[110]

335. McKinsey advised both Purdue and Endo contemporaneously for more than a decade. With each client, the goal was the same: to maximize opioid sales. The work McKinsey performed for each client was so similar that there was routinely confusion internally about whether a specific project or task to perform was for Endo or Purdue.[111]

336. Despite McKinsey's emphasis on confidentiality, the fact that McKinsey repeats its work from one client to the next is well-known to the client. Indeed, it is part of the justification in hiring McKinsey in the first place. McKinsey can tell you what everyone else is doing. [redacted][112]

337. McKinsey's earliest known work with Endo [redacted]. In a November 22, 2006 presentation[113] entitled "[redacted]" McKinsey advised [redacted]

[110] MCK-MDL2996-0062712.

[111] In response to an internal email from Craig MacKenzie to other McKinsey consultants seeking "expert input on labels for abuse deterrent formulations" in conjunction with McKinsey's work on the Belbuca launch (discussed *infra.*), McKinsey consultant Jeff Smith replied, "Craig – is this for Purdue or Endo? If for Endo, I am conflicted." MCK-MDL2996-0383805.

[112] ENDO-OPIOID-MDL-07619243.

[113] The McKinsey presentation was [redacted]" ENDO-OPIOID_MDL-02936031. By 2007, McKinsey had [redacted] ENDO-OPIOPID_MDL-06078889. Endo acquired Penwest in 2010. "Endo Pharmaceuticals Agrees to Acquire Penwest Pharmaceuticals," Fierce Biotech, August 10, 2010, *available at*: https://www.fiercebiotech.com/biotech/endo-pharmaceuticals-agrees-to-acquire-penwest-pharmaceuticals

[redacted][114]

338. McKinsey noted, [redacted].[115]

339. McKinsey also [redacted][116]

340. McKinsey advised [redacted][117]

341. McKinsey even [redacted][118]

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[114] ENDO-OPIOID_MDL-02936031.
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*

342. Within a few years of its introduction in the United States, abuse of the drug became widespread. Endo then sought to introduce a reformulated version of Opana that it could market as abuse-deterrent by introducing a tamper-resistant coating to the pill.

343. In December 2011, Endo obtained FDA approval for a new formulation of Opana ER with the coating that Endo claimed was crush-resistant. The following month, however, the FDA told Endo that it could not market Opana ER, even after the reformulation, as abuse-deterrent.

344. Endo "did not submit any new clinical safety or efficacy data" as part of its application, but rather relied entirely on the "bioequivalence" of the new and old formulations of Opana. Obtaining approval of reformulated Opana ER on this basis allowed Endo to rely on the safety and efficacy of the original version of the drug as the basis for approval of the reformulated version.[119] The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. In December 2011, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."[120]

345. In 2013, an Endo training module directed key opinion leaders to instruct prescribers that OPANA ER with INTAC is the only oxymorphone designed to be "crush-resistant," and advised the key opinion leaders to state during their speeches that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe OPANA ER with INTAC."[121] The speakers were advised to stress that generic versions of Oxymorphone "are not designed to be crush-resistant."

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[119] Intervenor Impax Laboratories, Inc.'s (1) Cross-Motion to Dismiss; or, in the Alternative, (2) Opposition to Plaintiff's Motion for a Preliminary Injunction, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.* ("Impax Br."), No. 1:12-cv-01936 Doc. 18 at 7 (D.D.C. Dec.9, 2012); *see also* FDA Summary Review for Regulatory Action, NDA 201655 (Dec. 9, 2011) (stating that "[n]o new safety data were included in this submission" and "[n]o efficacy studies were submitted in this application.").

[120] Endo Dec. 12, 2011 News Release; Ex. A to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 Doc. 18-2 (D.D.C. Dec. 9, 2012).

[121] EPI000421543.

346. These abuse-deterrent attributes of the reformulation—the very characteristics McKinsey and Endo touted as a reason to prescribe Opana—were a sham. The reformulation was designed to prevent the pill from being crushed and snorted through the nose. It did not prevent intravenous use, however. The result was that many users already dependent of Opana began using needles to inject the drug for the first time. As an internal Endo email put it, [redacted][122]

347. Endo's 2012 reformulation of Opana caused outbreaks of HIV in populations of intravenous Opana users. In Austin, Indiana, where Jeff and Joy resided, Opana was linked to an outbreak of at least 200 HIV cases in a town with a population of 4,500.[123]

348. Intravenous use of reformulated Opana has also been associated with outbreaks of Hepatitis C and Thrombotic Thrombocytopenic Purpura ("TTP").[124] The concerns even reached Wall Street, where an analyst asked Endo about a TPP outbreak in Tennessee associated with Opana ER. Endo assured the analyst that the outbreak was, like the outbreak in Indiana, in "a very, very distinct area of the country."

349. McKinsey was well aware, as was Endo, of these problems. [redacted][125]

350. In June of 2013, McKinsey [redacted]

[122] END00010732.
[123] *Id.*
[124] "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013).
[125] ENDO00260151.

[redacted].[126]

351. McKinsey indicated that [redacted][128]

352. In addition to being neither feasible nor safe/ethical, the study was beside the point. An insufflation study is meant to determine the abuse characteristics of a drug when used nasally—i.e., by snorting the drug.[129] The relevant concern for Opana's reformulated version was *injection*, not insufflation.

353. But the insufflation study worked for Purdue. Going forward, McKinsey suggested [redacted][130]

354. As the preceding paragraphs make clear, Endo and McKinsey were laser-focused on maximizing overall sales of Endo products, and decidedly *not* on concerns over their actual abuse potential or the appropriate *size* of the market for these products, given evident, longstanding, and ever-present concerns about their abuse. To the point, McKinsey regarded concerns about opioid abuse only as a means by which its clients could introduce *differentiated* products (i.e., those with purported abuse-deterrent or tamper-resistant features) to continually perpetuate overall opioids sales for their clients. In all instances, the parties desired for the size of

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[126] EPI002107711.
[127] *Id.*
[128] *Id.* (emphasis added).
[129] *See* General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products, FDA Center for Drug Evaluation and Research, November 2017, *available at*: https://www.fda.gov/files/drugs/published/General-Principles-for-Evaluating-the-Abuse-Deterrence-of-Generic-Solid-Oral-Opioid-Drug-Products-Guidance-for-Industry.pdf.
[130] EPI002107711.

that overall opioids market to grow in line with the introduction of "differentiated" products like a reformulated Opana.

355. Endo's purported concern about deterring abuse of its drugs was laid bare as farce by a particularly striking decision: to continue to sell the old formulation of Opana despite touting the notion that the old formulation was purportedly dangerous in ways that the new formulation was not. Endo [redacted].[131]

356. Endo not only continued to distribute original Opana for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers.[132] In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[133]

357. In June 2013, an Endo employee informed the McKinsey consultants of a [redacted][134]

2. <u>Belbuca: Endo's Answer to Butrans</u>

358. Buprenorphine is another differentiated product. Opioid manufacturers began to introduce Buprenorphine products to the market after the introduction of OxyContin, Opana, and other branded opioids long-known to have abuse and dependency problems. Buprenorphine products were marketed as purportedly less dangerous than products such as OxyContin or Opana.

359. Of course, Endo and Purdue continued to assiduously market and sell OxyContin and Opana alongside their Buprenorphine products, and McKinsey worked with each at every

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[131] ENDO-OPIOID-MDL-02324795.
[132] Impax Br. at 1.
[133] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).
[134] ENDO-OR-CID-00400235 (emphasis added).

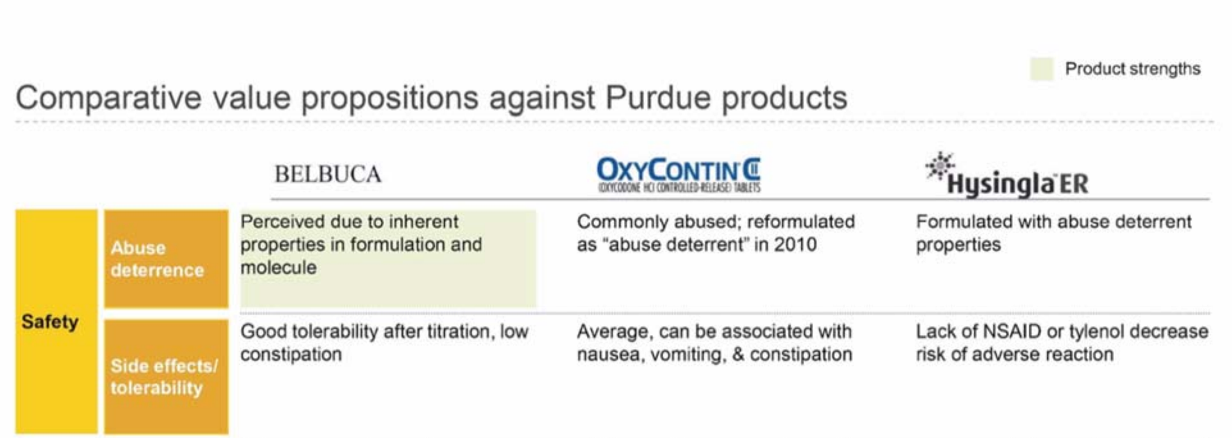
step of the way, despite the implicit contradiction in marketing two products at the same time whose point of differentiation is one being *less addictive and dangerous* than the other.

360. For example, on August 13, 2015, McKinsey's Craig MacKenzie circulated a discussion document to Endo and McKinsey staff entitled "Belbuca value proposition," which laid out McKinsey's thoughts on how to differentiate Endo's buprenorphine product from other opioids in the marketplace.[135] One point of differentiation McKinsey noted was that OxyContin was commonly abused, while Endo's Belbuca hopefully would not be: [136]

361. The cognitive dissonance was palpable. At the same time that MacKenzie sent his email differentiating Belbuca, and as described *supra*, McKinsey was *also* maximizing OxyContin sales for Purdue—the opioid it was describing to Endo as commonly abused.

362. [redacted] Butrans was Purdue's buprenorphine product.

363. Once Butrans was launched at Purdue, McKinsey worked with Endo to create another branded Buprenorphine product to compete with Butrans. These product planning and launch processes are long-term affairs. McKinsey worked with Endo on this project for *four years* before Endo's Belbuca obtained FDA approval.



364. McKinsey remained in place at Endo to implement the launch of Endo's Buprenorphine product. The strategic goal of Belbuca—the key to its commercial success—was

[135] MCK-MDL2996-0410742.
[136] MCK-MDL2996-0006669, at 0006675.

to convert short acting opioid ("SAO") users to Belbuca. As McKinsey explained to CEO Rajiv de Silva, "The fundamental question is whether Belbuca will take share from the short-acting opioids."[137]

365. Ultimately, Belbuca was not a large commercial success for Endo because it failed to transition a sufficient number of short acting opioid users to the long-acting Belbuca. As the drug underperformed, Endo felt ever more pressure to stimulate sales. John Harlow described one meeting with de Silva on April 8, 2016: "We just got out of the review with Rajiv and clearly our TRx trends are not good and are behind other recently launched pain products . . . the request from Rajiv was to do anything possible that could be implemented ASAP to stimulate RXs."[138]

366. By July 6, 2016, McKinsey and Endo were increasingly focused on converting short-acting opioid users. [redacted][139] Notably, the goal was to increase *overall* buprenorphine prescriptions, not only those of Belbuca. The discussion document identified an objective to create "a new treatment paradigm for [Buprenorphine] and Belbuca at the transition between SAO and LAO."[140] In order to do so, the discussion group needed to determine "what medical support we need to position Buprenorphine as the best transition from SAO to LAO."[141]

367. McKinsey provided a slide to Endo describing the way that narrative would first be *created* and then exploited for market positioning:[142]

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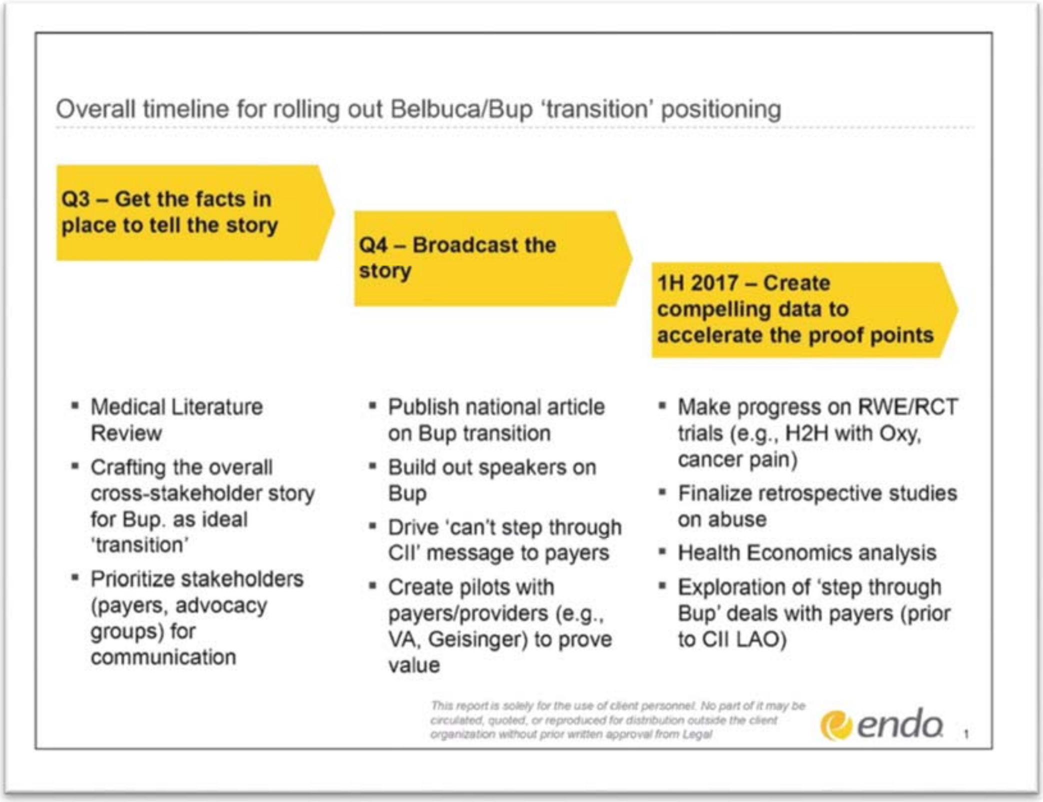
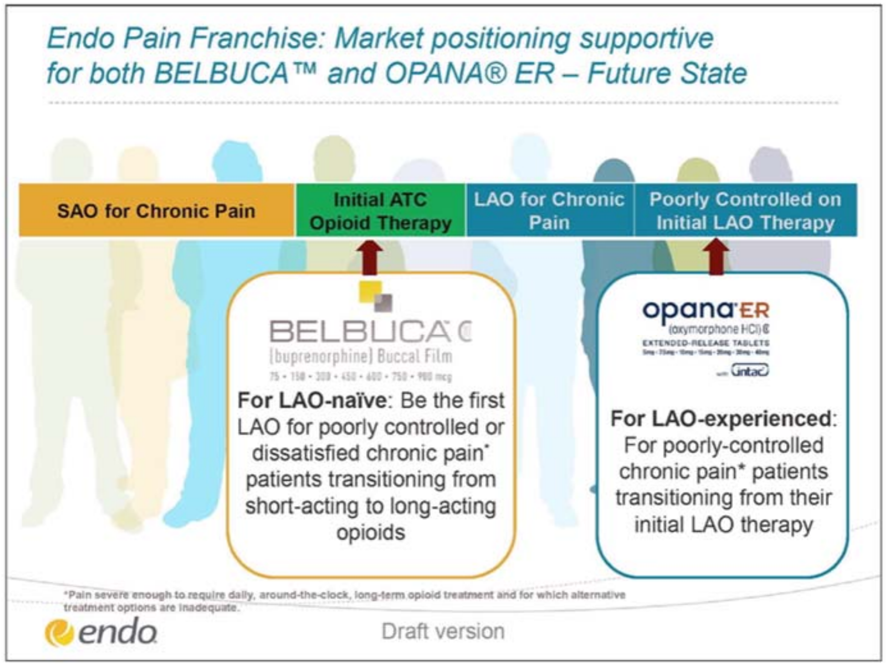
[137] MCK-MDL2996-0210158.
[138] MCK-MDL2996-0358973, at 0358975.
[139] ENDO-OPIOID_MDL-07264539
[140] *Id.*
[141] *Id.*
[142] MCK-MDL2996-0382731.



368. McKinsey and Endo referred to this effort to revive Belbuca sales by promoting buprenorphine as a bridge to long-acting opioid use as a "moonshot."[143] One aspect of this "moonshot" would be that Belbuca (and Buprenorphine, generally) would convert short-acting opioid users to long-acting opioids users of products *other than Buprenorphine*. McKinsey and Endo instead conceived of Belbuca as an "*Initial* ATC Opioid Therapy." It was to be positioned as "the *first* LAO for poorly controlled or dissatisfied chronic pain patients transitioning from short-acting to long-acting opioids." Patients could eventually transition from Belbuca to other long-acting opioids, like Opana:[144]

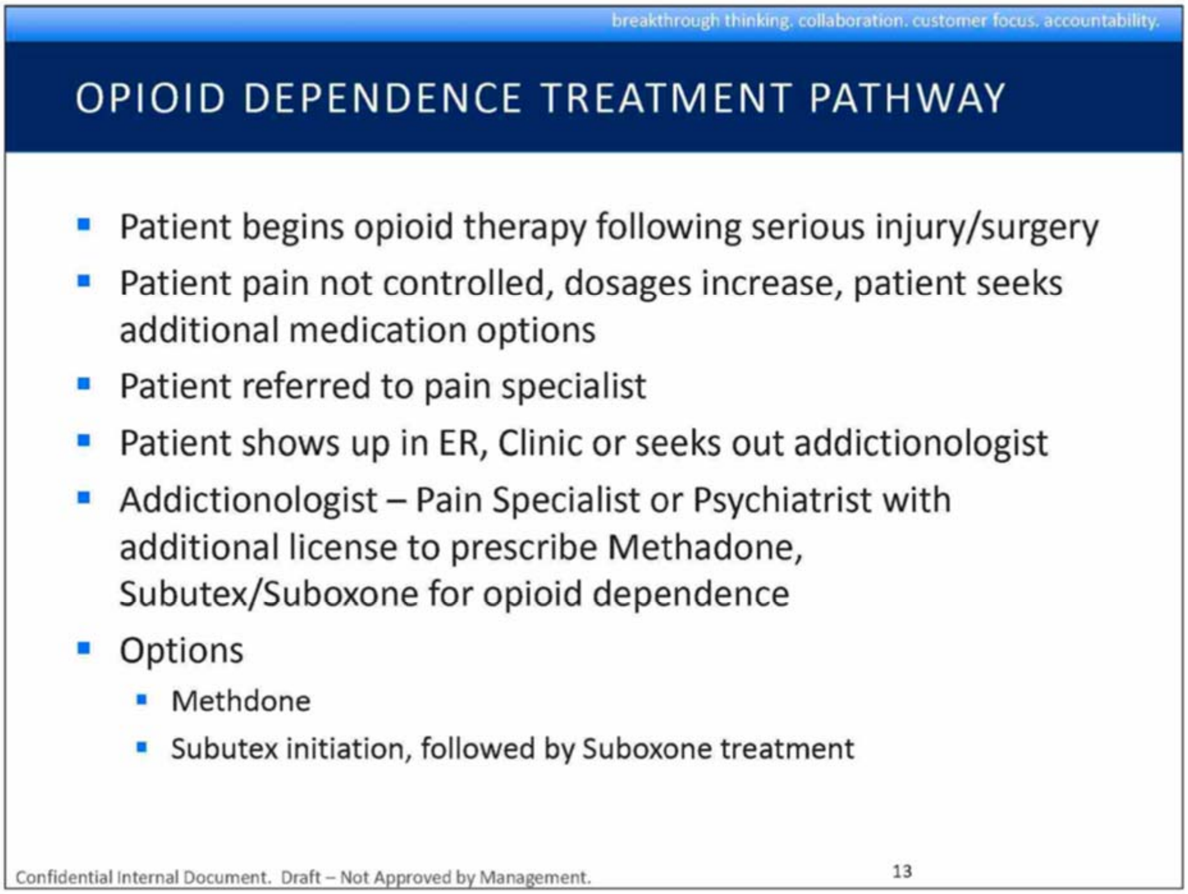
[143] MCK-MDL2996-0382412.
[144] MCK-MDL2996-0404374, at 0404375.



369. Thus, the overall marketing strategy McKinsey assisted Endo in designing and deploying for Belbuca was designed to transition ever more patients to long-acting opioids. Belbuca could find its market niche as a stepping stone as individuals proceed through the patient funnel from short acting opioid users to longer-term long-acting opioid users. The farther an individual proceeds through this funnel, the more the individual is worth.

370. McKinsey also knew that this same pathway that begins with opioid therapy after a serious injury also leads to opioid dependency and addiction. In 2011, McKinsey was working on "Project X." which was the project to develop a buprenorphine product to compete with Butrans. (Belbuca, in other words, was the result of Project X.) McKinsey described the "opioid dependence treatment pathway" as follows:[145]

[145] MCK-MDL2996-0131500, at 0131512.



371. In the same presentation, McKinsey identified the key to a successful launch of a branded Buprenorphine product: "The challenge faced by Endo will not be to gain formulary approval, it will be to gain tier 2 status and *minimize restrictions on prescribing*."[146]

3. <u>Turbocharging the Sales Force with a Blitz</u>

372. In 2015, a McKinsey team led by Arnab Ghatak proposed to Endo a sales transformation to invigorate Endo's product sales, including its opioids. At the suggestion of Ghatak, McKinsey used the Purdue Pharma Project Turbocharge model from the previous year as a template for the Endo proposal.[147] Even the PowerPoint presentations used to create the proposal to Endo were drafted off the Project Turbocharge slides. On June 28, 2015, Sherin Ijaz of McKinsey emailed Ghatak, Nicholas Mills, and Laura Moran to circulate a draft proposal for an "Endo sales force transformation" PowerPoint presentation. Ijaz explained, "Laura, I heavily

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[146] MCK-MDL2996-0131500, 0131525 (emphasis added).
[147] MCK-MDL2996-0075895.

leveraged what you send (sic) from Purdue as it was all applicable."[148] All three of the recipients of Ijaz's email regarding the Endo proposal had been working on the Purdue account for years.

373. Endo [redacted][149]

374. Endo's Vice President & General Manager of its Pain Business Unit, John Harlow, [redacted][150] [redacted][151]

375. The Endo and Purdue proposals were essentially identical sales transformations. The goals were the same: to maximize sales of opioids. Merely the names were changed. While McKinsey offered to "turbocharge" Purdue's sales force, McKinsey proposed a "sales force blitz" for Endo.[152]

376. In fact, the names weren't *entirely* changed. [redacted].[153]

377. [redacted]

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[148] MCK-MDL2996-0070237.
[149] ENDO_AAC_00363406.
[150] *Id.*
[151] *Id.*
[152] *E.g.*, MCK-MDL2996-0130803; MCK-MDL2996-0132851.
[153] MCK-MDL2996-0069747, at 0069749.

[redacted]

378. [redacted]

379. Upon McKinsey's suggestion, Endo began reallocating sales force resources to Opana from other Endo products such as Sumavel, a migraine medication, and Voltaren, an anti-inflammatory.[154] Writing to the McKinsey team, Endo's Alicia Logan stated the joint mission, "I agree that our main goal is to maximize the increased promotional efforts for [Opana ER] without disrupting/sacrificing [Sumavel] or [Voltaren] TRx volume and it appears that we [can] accomplish this with your recommendation of addition another 500 targets."[155]

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[154] MCK-MDL2996-0409466.
[155] MCK-MDL2996-0409436, at 0409437 (sic).

380. With the Sales Force Blitz underway, Endo received good news in New York. Years prior, Endo had initiated patent litigation against generic manufacturers of Opana ER, arguing that the generic versions of the drug infringed on Endo's patents. In part because of the perceived impending loss of exclusivity, Endo had in recent years allocated its sales force capacity away from Opana and to other Endo products.

381. On August 14, 2015, Endo received a favorable initial ruling declaring that the generic versions of Opana violated Endo's patents, and enjoined their further sale. The ruling provided additional patent exclusivity for Opana, and Endo was keen to exploit its advantage.

382. That afternoon, [redacted][156]

383. The following week, Harlow wrote to the McKinsey team working for Endo to focus their attention on Opana ER. "Now with our litigation victory from last week, plus our UHC opportunity, there is an increased need to increase FF support to drive Sep-Dec business. . . . With this win, I am now willing to go broader with OER targeting."[157]

4. McKinsey's Targeting of Hospitals in Regions Hit Worst by Opioids for Endo

384. As part of McKinsey's strategy of increasing Endo opioid sales and prescriptions by any means necessary, [redacted]

385. [redacted]

[156] ENDO-OPIOID_MDL-02279530.
[157] MCK-MDL2996-0358871, at 0358872; ENDO-OPIOID_MDL-02201117.

[redacted]

386. McKinsey targeted deals with large healthcare facilities [redacted]

[redacted]

387. [redacted]

388. [redacted] Uncoincidentally, these regions have been hit

hard by the opioid epidemic. This was long after McKinsey was aware of the diversion and abuse problems in these markets.

389. [redacted]

390. In October 2014, Scott County, Indiana, faced a serious HIV outbreak affecting 181 people and was linked to injection abuse of Opana. This HIV outbreak led to then-Governor Mike Pence actually supporting and establishing needle exchanges in 2016 to try to curtail the HIV and other blood-borne infections spread by Opana. This HIV outbreak is cited as the main factor when the FDA pulled the approval for Opana, which eventually Endo completely withdrew from the market.

G. McKinsey's Opioid-Related Work with Other Clients

391. Part of the unique value McKinsey provides is its deep knowledge of its clients' competitors, often because it counts those same competitors as its clients. McKinsey generally does not disclose to its clients its work for their competitors, but every company that enters into the Master Consulting Agreement understands and acknowledges that McKinsey may use the client's confidential information for the benefit of the client's competitors as long as McKinsey does not directly divulge the information to competitors.

392. McKinsey specifically worked to [redacted][158]

393. McKinsey worked with numerous other manufacturers to promote the sale of opioids. To date, Plaintiffs have identified as McKinsey clients [redacted][159] and [redacted][160]

394. Coordination among these industry participants was a natural outgrowth of the fact that McKinsey had existing client relationships with each participant. For instance, on May 7, 2009, Richard Sackler's personal counselor, McKinsey partner Maria Gordian, [redacted][161]

395. [redacted][162]

[158] MCK-MDL2996-0041741.
[159] MNK-MDL_001756041; MNK-T1_0000968026; MN-T1_0004715842; MNK-T1_0005985720.
[160] TEVA_CHI_00187019.
[161] TEVA_CHI_00187019.
[162] TEVA_CHI_00187023.

396. [redacted][163]

[redacted]

397. McKinsey provided substantial assistance and encouragement to its manufacturing clients to frustrate the FDA's goals in putting effective REMS measures in place.

398. One example of how this directly impacted NAS babies [redacted]

[163] *See* ALLERGAN_MDL_00637407.

[redacted]

[redacted]

[redacted]

[redacted]

1. McKinsey's Work with Opioid Distributors

399. McKinsey substantially assisted and encouraged opioid distributor AmerisourceBergen [redacted] so as to violate the Controlled Substances Act.[164]

400. McKinsey substantially assisted and encouraged opioid distributor McKesson [redacted] so as to violate the Controlled Substances Act.[165]

401. Upon information and belief McKinsey substantially assisted and encouraged opioid distributor Cardinal to increase sales of generic pharmaceuticals, and drive opioid supply into the diversionary market including fentanyl, so as to violate the Controlled Substances Act.[166]

2. McKinsey's Work with the FDA

402. As described above, McKinsey assisted Purdue and others to confront FDA regulations that posed threats to their clients' ability to maximize revenues from their opioid products. McKinsey's role in shepherding its clients through regulatory interactions takes on a

[164] ABDCMDL12135609, slide 5.
[165] ABDCMDL12135609, slide 5.
[166] ABDCMDL12135609, slide 5.

different hew when considered in light of one of McKinsey's other clients: the Food and Drug Administration itself.

403. Indeed, the FDA has proved a massive client for McKinsey, who since 2000 has endeavored to expand its public sector practice under the direction and leadership of Nancy Killefer, a now-retired senior partner and director of the firm.[167] Since 2008, the FDA has paid McKinsey more than $140 million.[168] A significant portion of that work for the FDA related to the FDA's Center for Drug Evaluation and Research ("CDER"). The CDER is the principal division tasked with approving, among other classes of drugs, opioids. Since 2008, McKinsey has been awarded at least 17 contracts worth at least $48 million for CDER work.[169]

404. The REMS protocols, discussed above, that McKinsey assisted Purdue and others in surmounting beginning in 2008 and culminating in 2012, were overseen by CDER.[170]

405. Meanwhile, in 2010, McKinsey advised the FDA on building a monitoring system called "track and trace" to assist in the identification of potentially improper distribution of harmful prescription drugs, such as opioids. "The 'track and trace' system deeply impacted McKinsey clients, including the nation's three largest drug distributors—McKesson, AmerisourceBergen, and Cardinal Health [where Killefer has been a director since 2015]."[171]

406. Under one contract, McKinsey developed a roadmap and implemented plans to modernize CDER's new drug regulatory program. Under another, McKinsey developed a framework to increase information technology project delivery across CDER.[172]

407. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which placed new restrictions on the use of certain high risk prescription drugs, including opioids. The new law mandated that FDA require manufacturers of certain drugs to create REMS.

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[167] Duff McDonald, *The Firm*. Killefer is also a director of Cardinal Health, one of the distributor defendants in the ongoing nationwide opioid litigation, and a company subject to FDA regulations.
[168] Letter to Dr. Janet Woodcock from Senator Margaret Hassan et al, August 23, 2021, *available at*: https://www.hassan.senate.gov/imo/media/doc/fda-mckinsey_letter-final-210823.pdf ("Hassan Letter")
[169] *Id.*
[170] *Id.*
[171] *See* http://cg.cardinalhealth.com/board-of-directors/default.aspx; Hassan Letter.
[172] Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*: https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

408. The FDAAA also required the Secretary of Health and Human Services "to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs." 21 U.S.C. § 355e(a).

409. In 2010 and 2011, under the FDAAA, the FDA awarded McKinsey contracts to design a "track and trace" system to monitor prescription drugs, including opioids, throughout the supply chain and to streamline the drug approval process. The track and trace system had the greatest effect on drug distributors, including McKinsey clients McKesson, AmerisourceBergen, and Cardinal Health.[173]

410. Under these contracts, McKinsey was required to consult with "supply chain stakeholders," which likely included these three McKinsey clients as well as pharmaceutical manufacturers.[174]

411. In 2011, McKinsey also won a $1.8 million contract with CDER's Office of Surveillance and Epidemiology ("OSE"), which monitors and evaluates the safety profiles of drugs available to American consumers.[175] OSE "evaluates more than 2 million adverse event reports submitted every year to FDA's MedWatch program" and provides "risk management expertise on development and implementation of programs and initiatives to support [CDER's] policies related to [REMS] authorities.[176]

412. The OSE contract tasked McKinsey with a widespread mission of understanding how OSE functions within the context of a broader system of drug safety in CDER and ultimately developing and implementing a new operating model. In other words, McKinsey helped to restructure a key body that has oversight over the opioid supply chain.

413. The 2012 Food and Drug Administration Safety and Innovation Act required the FDA to modernize Sentinel, a system meant to monitor the safety of drugs once they are on the

[173] Hassan Letter.
[174] *Id.*
[175] https://www.documentcloud.org/documents/21071060-mckinsey-ose-contract
[176] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology

market.[177] According to the FDA, "Sentinel generates *real-world evidence* to support regulatory actions aimed at protecting the public's health," which in turn "inform[s] healthcare provider decision-making for patients."[178]

414. A 2014 contract with the FDA charged McKinsey with assessing the "strengths, limitations and appropriate use" of Sentinel. Like the track and trace contract, the Sentinel project required McKinsey to interview "external stakeholders," including "industry organizations" and "drug and device industry leaders."[179] McKinsey also evaluated how the FDA employees used Sentinel to inform regulatory decision making.[180]

415. McKinsey performed similar work for the FDA as recently as 2019,[181] when it signed a contract extension with the agency for work relating to the FDA's efforts to modernize the process by which it regulates new drugs.[182]

416. The FDA's drug tracking programs have been panned as failures.[183]

417. A theme was emerging: as new legislation and regulatory systems were enacted that could have hampered the opioid supply chain, McKinsey stepped in as a key consultant for the FDA. Each time, the new system failed to reign in the out-of-control opioid market. While the FDA was not solely responsible for regulating the opioid industry and McKinsey was not wholly responsible for the FDA's inaction, tools like Sentinel and track and trace could have been implemented in a way to provide new information to combat the country's growing opioid crisis.

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[177] https://www.documentcloud.org/documents/21071047-r_sentinel_assessment_award_contract_sow-redacted-pr.

[178] https://www.fda.gov/files/about%20fda/published/Sentinel-System-Overview—-Presentation.pdf; https://www.healthaffairs.org/do/10.1377/hpb20150604.936915/full/.

[179] Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency," *ProPublica* (Oct. 4, 2021), *available at* https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency.

[180] Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, *available at*: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf.

[181] Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency," *ProPublica* (Oct. 4, 2021), *available at* https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency.

[182] Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, *available at*: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf.

[183] Sabrina Tavernise, "F.D.A. Faulted for Problems With Drug Tracking" *The New York Times*, Jan. 14, 2016, *available at* https://www.nytimes.com/2016/01/15/health/fda-faulted-for-problems-with-drug-tracking.html; https://www.gao.gov/assets/gao-16-192.pdf.

418. At the same time McKinsey was consulting for the FDA, it was working with its opioid industry clients on how skirt the FDA's regulatory systems.

419. For example, McKinsey advised Purdue on how to soften the FDA's proposed REMS and on coordinating with other opioid manufacturers to advocate against strict oversight.[184] The finalized REMS for opioid products was largely devoid of the restrictions that FDA had initially proposed.[185]

420. McKinsey's work with the FDA was a key factor in why pharmaceutical industry clients tapped McKinsey for FDA-related work. For example, in endorsing McKinsey's proposed strategy of banding together with other opioid manufacturers, Purdue CEO John Stewart suggested that the consultant itself facilitate the pharmaceutical group's approach to FDA. He wrote: "Perhaps a consultant such as McKinsey who did similar work in the industry and FDA on some aspects of clinical trials or a healthcare-related group that would be interested in playing an active role in the program's development and delivery would be a good choice."[186]

421. McKinsey performed work for the FDA without disclosing its potential conflicts of interest to the FDA in violation of the contracts between the company and the agency.

422. The FDA typically includes conflict of interest clauses in its contracts and relies on contractors to assess and report any conflicts. McKinsey's contracts with the FDA related to CDER processes contained such provisions. One contract required McKinsey to "make an immediate and full disclosure, in writing, . . . of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the contractor's impartiality because of the appearance or existence of bias."[187]

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[184] Hassan Letter.
[185] Hassan Letter; Maloney Letter.
[186] Purdue Bankruptcy, Doc. 2166-5, at 58-59.
[187] Ian MacDougall, McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency, *ProPublica* (Oct. 4, 2021), available at https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency.

423. But McKinsey never disclosed its work on behalf of opioid supply clients to the FDA despite having a hand in developing some of the FDA's most important regulatory processes.[188]

424. Disclosing its conflicts might have turned off the lucrative tap to not only FDA contracts but also to pharmaceutical industry clients, given the clear value such clients placed on McKinsey's work for the FDA.

425. McKinsey's manipulation of regulatory requirements—whether to skirt its own contractual requirements or to bend processes that regulate its clients—is nothing new. McKinsey has come under fire from the Office of Inspector General for the General Services Administration for contract procurement violations[189] and from the Justice Department related to violation of Chapter 11 bankruptcy rules.[190] Most recently, six senators have begun to investigate the relationship between McKinsey and the FDA[191] the House Committee on Oversight and Reform is exploring its abusive conduct in connection with the opioid industry.[192]

426. As one commentator noted, McKinsey's conduct suggests that it "behaves as if it believes the rules should bend to its way of doing things, not the other way around."[193]

H. <u>McKinsey's Efforts to Increase the Overall Size of the Opioid Market: the Larger the Pie, the Larger the Slice</u>

427. McKinsey advised multiple opioid manufacturers regarding how to grow opioid sales. In order to benefit the entire opioid industry, McKinsey engaged in efforts to grow the entire opioid market, and not only each individual client's share of it. The theory, basically, is that a rising tide lifts all boats.

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[188] *Id.*; Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*: https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf.
[189] Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), available at https://www.propublica.org/article/how-mckinsey-makes-its-own-rules.
[190] Mary Williams Walsh and Emily Flitter, McKinsey Faces Criminal Inquiry Over Bankruptcy Case Conduct, *New York Times*, Nov. 8, 2019, *available at* https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-investigation-bankruptcy.html.
[191] Hassan Letter.
[192] Maloney Letter.
[193] Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), available at https://www.propublica.org/article/how-mckinsey-makes-its-own-rules.

428. For example, Purdue incentivized its sales staff "to increase not just sales of OxyContin but also generic versions of extended release oxycodone." Typically, one would not wish to encourage the sales of generic competitors that offer a similar product to one's own. If, however, the goal is to position a company so as to look like an attractive acquisition target, the growth of the overall opioid market is just as important as one's own market share: "Whereas pharma salespeople are usually compensated based on their ability to grow sales of a particular medicine, part of the bonus for Purdue's staff was calculated in relation to the size of the overall market."[194] McKinsey designed that plan.[195]

429. This notion that the size of a company's market share is not as important as the size of the *overall* market in which it competes is a core insight of McKinsey's granular approach to identifying corporate growth opportunities. Describing their authors' conclusions in *The Granularity of Growth,* McKinsey stated, "One of their most surprising conclusions is that increased market-share is seldom a driver of growth. They contend, instead, that growth is driven by where a company chooses to compete: which market segments it participates in . . . the key is to focus on granularity, to breakdown big-picture strategy into its smallest relevant components."[196]

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[194] *See* David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

[195] Worth noting is that this strategy of increasing overall opioid sales directly benefitted the Sacklers through their ownership of Rhodes Pharma, a generic opioid manufacturer. Naturally, McKinsey worked with the Sacklers in connection with Rhodes as well, including proposing ideas for synergizing Purdue and Rhodes. *See, e.g.*, MCK-MDL2996-0324955; MCK-MDL2996-0285201. Especially worth noting is that this strategy also benefitted McKinsey's other opioid clients as well. As one observer wrote: "They have a huge amount of inside information, which raises serious conflict issues at multiple levels," stated a former consultant, referring to McKinsey's influential role as advisor to multiple participants in a given industry, such as opioid manufacturing. It "puts them in a kind of oligarchic position." Michelle Celarier, *The Story McKinsey Didn't Want Written*, Institutional Investor, July 8, 2019, *available at:* https://www.institutionalinvestor.com/article/b1g5zjdcr97k2y/The-Story-McKinsey-Didn-t-Want-Written.

For example, in an August 15, 2013 presentation to Purdue management entitled "Identifying OxyContin Growth Opportunities," McKinsey noted that "McKinsey's *knowledge of the ways other pharma companies operate* suggests Purdue should reassess the roles of MSL and HECON Groups – and further drive the salesforce to be more responsive to formulary coverage changes." (emphasis added).

[196] *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, *available at*: https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth.

430. In other words, "Purdue's marketing force was indirectly supporting sales of millions of pills marketed by rival companies."[197] "It's the equivalent of asking a McDonald's store manager to grow sales of Burger King and KFC," stated a government official with the Department of Health and Human Services.[198]

a. The West Virginia Opioid Market, the Unborn, and McKinsey

431. Three of the named Plaintiffs were born in West Virginia: Hayden Travis Blankenship, on behalf of Z.D.B.B.; Timothy Lambert, on behalf of M.L.; and Cynthia Woolwine, on behalf of E.G.W. West Virginia bore an outsized impact[199] from the tortious and criminal acts of McKinsey's clients and that impact is apparent when one looks at the increasing incidence of NAS births in West Virginia. The increasing incidence of NAS in West Virginia corresponds to the specific acts and omissions of McKinsey as plead herein.

432. In West Virginia, the impact was dramatic, with NAS births multiplying **more than 100 fold in the Mountain State from 2000-2014, peaking at 51.2 NAS births per 1000** in 2014. This completely dwarfs the nationwide rate of NAS births during this same time period, with national rates peaking at the comparatively low number of 7 NAS births per 1000 in 2016.

433. In West Virginia, the number of prescriptions written and the number of opioid drugs dispensed during this time period is staggering: between 2008 and 2018, 2.6 million opioid pills were dispensed from the Tug Valley Pharmacy in Williamson, WV (Population 2,800 individuals), and 3.7 million hydrocodone pills were dispensed from a pharmacy in the tiny town of Kermit, WV, with a population of only 400 individuals, during this same time period. Westside Pharmacy in Oceana, WV (Pop. 1,394), where one Plaintiff filled her prescriptions, sold 7,939,772 opioid pills between 2006 and 2014, according to DEA tracking data.

434. The number of opioids in West Virginia during this time period is so vastly more than small communities such as Oceana and Kermit could even consume for medical purposes, that it is all but guaranteed many of these pills were used by women of childbearing age, many of

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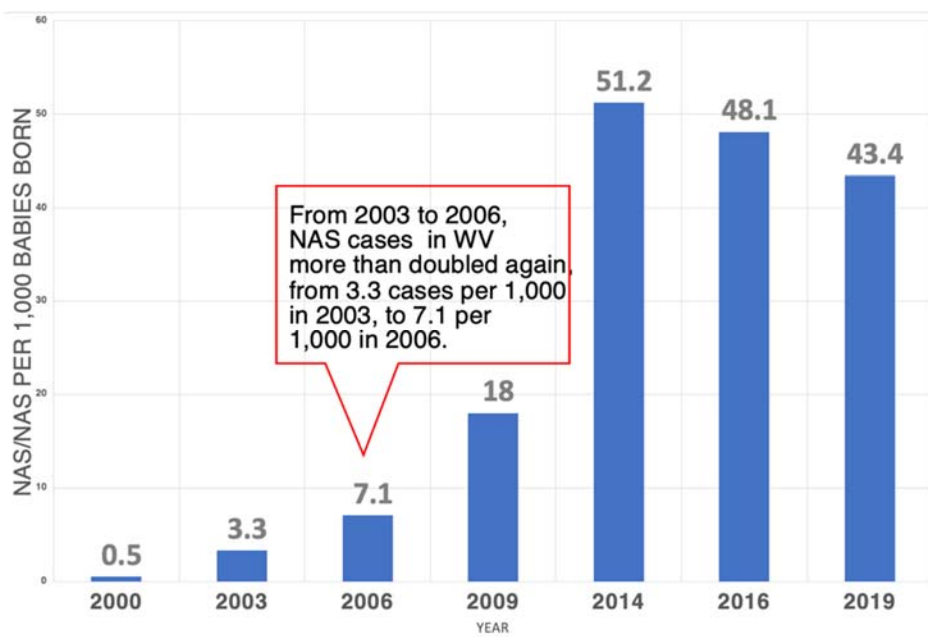
[197] *See* David Crow, *How Purdue's 'one-two' punch fueled the market for opioids*, Financial Times, Sept. 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.
[198] *Id*.
[199] "*Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virgina*", prepared by the U.S. House of Representatives Energy and Commerce Committee Majority Staff, Dec. 19, 2018 at 4.

which would become pregnant, continuing using opioids, some in the form of medication assisted treatment (MAT). There is also no doubt that a percentage of this massive number of pills entered the diversionary market, further increasing the severity of the opioid epidemic and the number of instances of NAS in West Virginia. This would not have been possible without McKinsey's advice to the pharmaceutical industry on how to sell the maximum number of opioids possible.

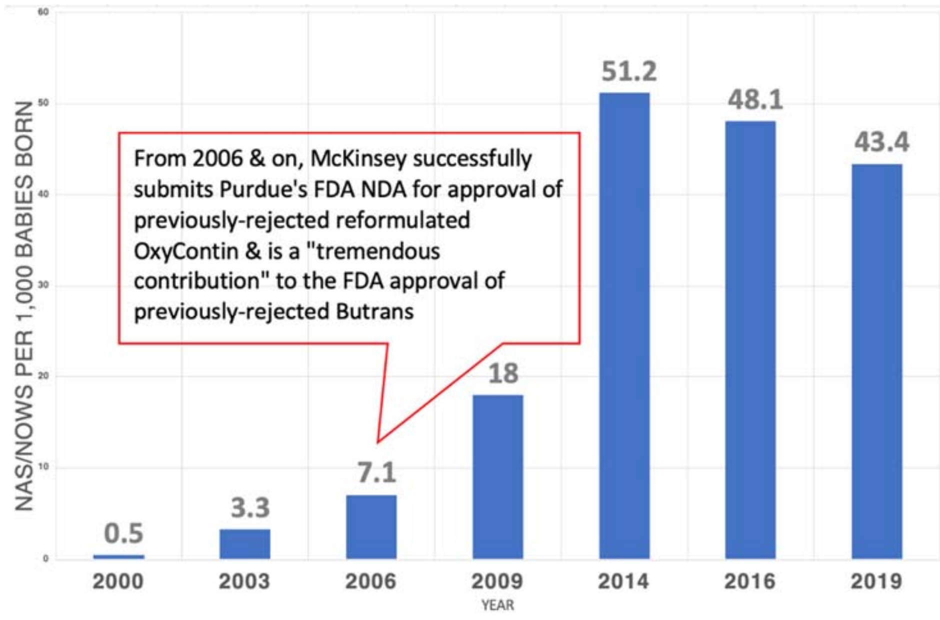
435. Comparing the rate of NAS births in West Virginia to McKinsey acts and omissions shows a linear relationship to McKinsey's action and injuries to the unborn.

436. As McKinsey's efforts to ramp up J&J and Purdue sales through the late 1990s to 2003 pump more opioids into West Virginia, NAS births leap almost 350%.

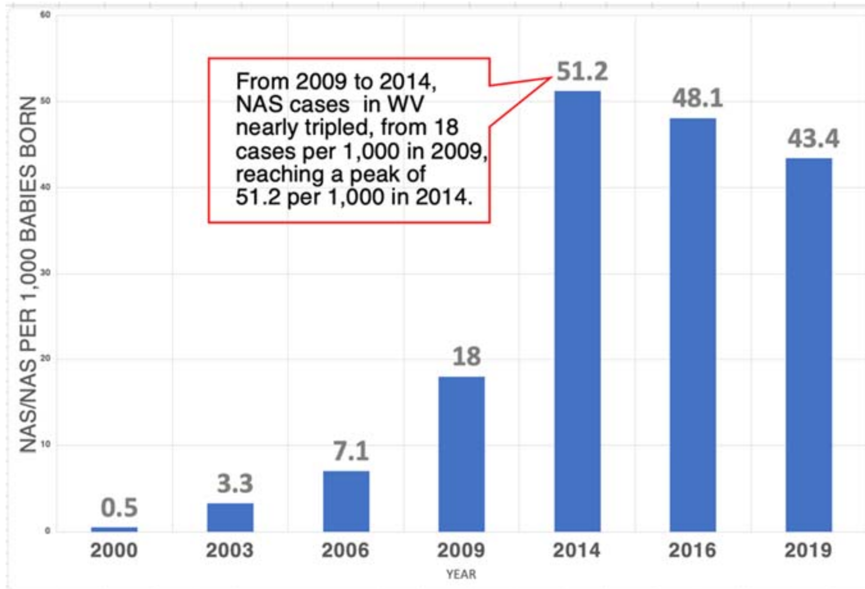
437. West Virginia NAS births more than doubled between 2004 and 2006, corresponding with McKinsey's efforts. Beginning in 2004 McKinsey oversaw Purdue's drug rep targeting high decile doctors prescribing J&J products.



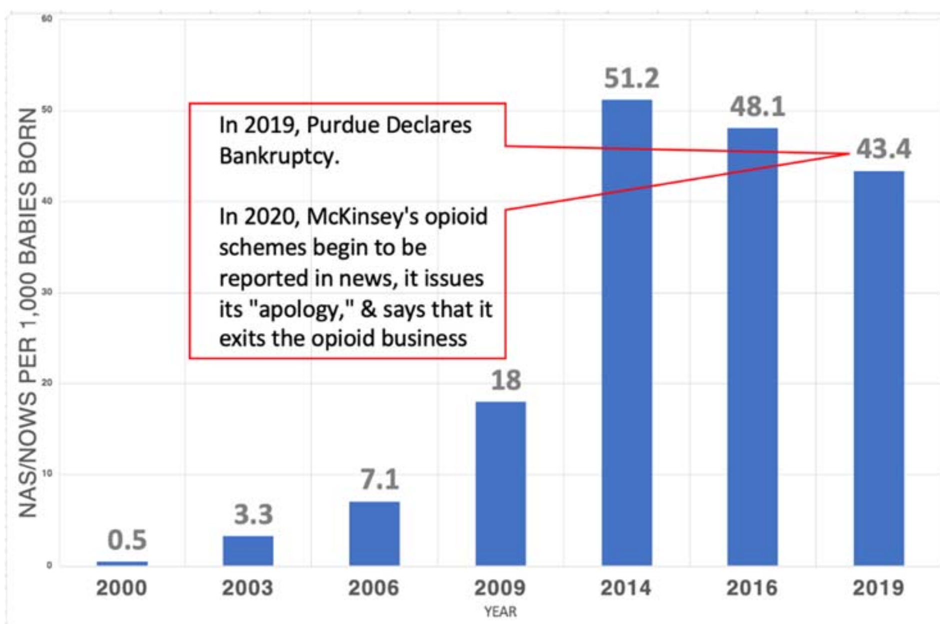
438. Between 2006 and 2009, again West Virginia NAS births more than doubled as McKinsey designs, directs, and oversees Purdue's efforts to secure approval for previously rejected applications for reformulated OxyContin and Butrans.



439. Between 2009 and 2014, NAS rates per 100,000 births again leapt 250% from 18 to more than 50. During this time McKinsey was openly driving both the demand for opioids in the diversionary market and the supply of opioids in the diversionary market by targeting high-decile prescribers for multiple clients in sequence, manipulating clinical trial data collected by its handpicked Contract Research Organizations and orchestrating REMS and Abuse Deterrent Formula efforts to maintain high profits for branded opioid manufacturers.



440. By 2020 NAS births in West Virginia stabilized at over 40 times the number of such births at the outset of McKinsey's involvement with Purdue. McKinsey by this time had publicly admitted that fetal opioid exposure causes long-term injuries to children, and McKinsey's acts and omissions were detailed in Purdue's guilty plea with the Department of Justice.



441. These alarming numbers of NAS births in West Virginia could not have been possible without McKinsey's schemes to increase opioid addiction among women of childbearing

age. According to the DEA ARCOS database ("ARCOS Data"), which tracks shipments of all opioid drugs from labelers and distributors to pharmacies on a national basis, between 2006 and 2012, the number of opioid drugs in West Virginia surged to these unprecedented levels as McKinsey's schemes were implemented by opioid manufacturers. According to this DEA data, the number of opioid drugs manufactured by Purdue Pharma and shipped to West Virginia during these years amounted to 952,781,390 milligrams of morphine equivalent ("MME"), or 16,919,660 individual pills or "total dosage units" ("TDU"). When divided by population, this equals to 515mg of morphine equivalent for each man, woman, and child in West Virginia.

b. <u>McKinsey Portrays Itself as Part of a Solution to a Problem It Was Integral in Creating.</u>

442. McKinsey's work on the other side of the aisle—helping clients address opioid abuse and addiction—further proves that it was well aware of the risks of OxyContin, and thus the risks of pushing OxyContin sales and high dose sales, and targeting the highest-volume prescribers. McKinsey advised Purdue on "Project Tango," a 2014 plan to enter the addiction drug market.[200] McKinsey noted the [redacted][201]

443. More than assisting specific clients with addressing the crisis itself, McKinsey saw the ongoing opioid crisis as an opportunity to posture itself as contributing more broadly to *society*. McKinsey likes to think of itself as a change agent capable of solving problems that truly matter, and the opioid crisis is one McKinsey realizes matters. Dr. Sarun Charumilind, a McKinsey partner in Philadelphia, "has led the firm's support to clients and *society* to combat the opioid crisis.[202]

444. In Detroit, partner Razili Lewis also helps "clients and *society* combat the opioids crisis." She does so by providing "insights, expertise, analytics, and technology."[203]

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[200] *See* David Armstrong, OxyContin Maker Explored Expansion Into "Attractive" Anti-Addiction Market, ProPublica (Jan. 30, 2019), *available at* https://www.propublica.org/article/OxyContin-purdue-pharma-massachusetts-lawsuit-anti-addiction-market.

[201] PPLPC023000714734.

[202] *See* https://www.mckinsey.com/our-people/sarun-charumilind.

[203] *See* https://www.mckinsey.com/our-people/razili-lewis.

445. Over in Cleveland, senior partner Tom Latkovic also "helps clients and *society* combat the opioid crisis."[204]

446. Kana Enomoto, a senior expert in Washington, D.C., is a "national leader in mental health and substance-use policy," who acted as a "content director" on a study to "raise awareness about opioid-use disorders." She also provided strategic guidance to the United States Surgeon General regarding efforts to "combat the opioid epidemic" when she was his Chief of Staff.[205]

447. McKinsey consistently states that it takes its obligations to society seriously. Indeed, the firm has established a center, to wit:[206]

> The Center for Societal Benefit through Healthcare was established to build on the long-standing mission of McKinsey's Public & Social Sector and Healthcare Systems & Services Practices to improve healthcare. The Center's work is funded solely by McKinsey; it is not commissioned by any business, government, or other institution. The Center brings a range of capabilities to bear, including McKinsey's healthcare expertise, advanced analytics, functional knowledge, technology assets, network, and investment capacity.
>
> The Center aspires to collaborate with other organizations to drive positive innovation to improve overall health and well-being and reduce healthcare disparities.

448. The Center has focused on addressing the impacts of the opioid crisis on society. One of the metrics that McKinsey uses to track the opioid crisis *as a matter of public health* is the "opioid prescribing rate" per 100 people in every county in the United States.[207]

449. As McKinsey's data visualization makes clear, there is an association between areas with higher opioid prescribing rates and higher instances of opioid use disorder.

450. The Center's data visualization is also reminiscent of similar work McKinsey did for Purdue in 2013, although the analysis McKinsey did for Purdue was more granular, analyzing opioid prescribing patterns on the *zip-code* level in all 50 states, as opposed to the county level:[208]

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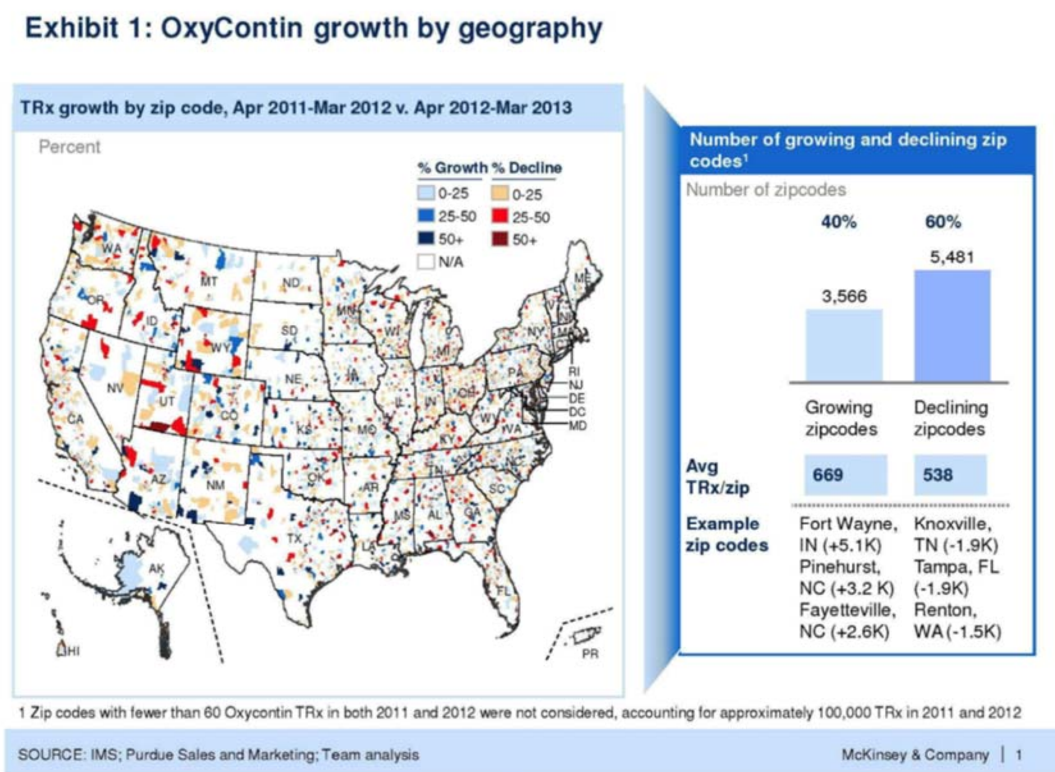
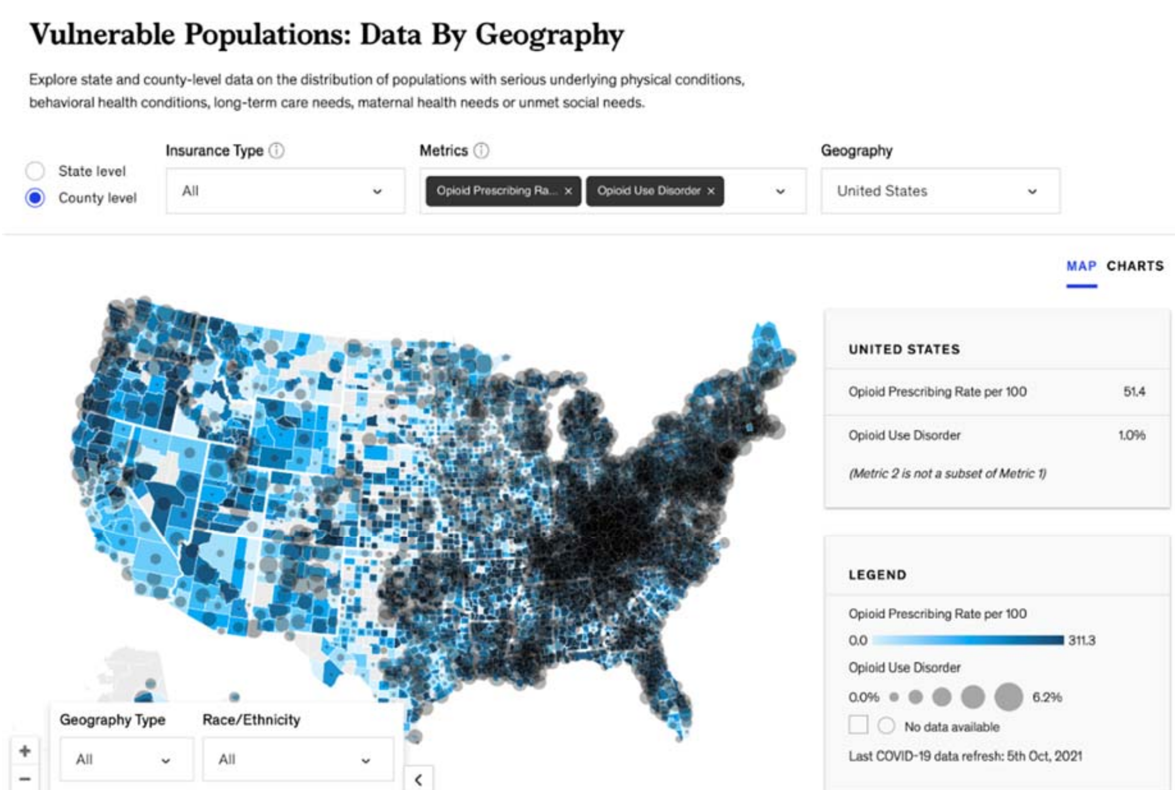
[204] *See* https://www.mckinsey.com/our-people/tom-latkovic.
[205] *See* https://www.mckinsey.com/our-people/kana-enomoto.
[206] *See* https://www.mckinsey.com/industries/healthcare-systems-and-services/how-we-help-clients/center-for-societal-benefit-through-healthcare/overview.
[207] *See* https://csbh-dashboard.mckinsey.com/#/data-insights?chart=SC&geo=County&lob=All&metric1=opioid_rxrate&metric2=oud&tab=Map.
[208] MCK-MAAG-0024283.

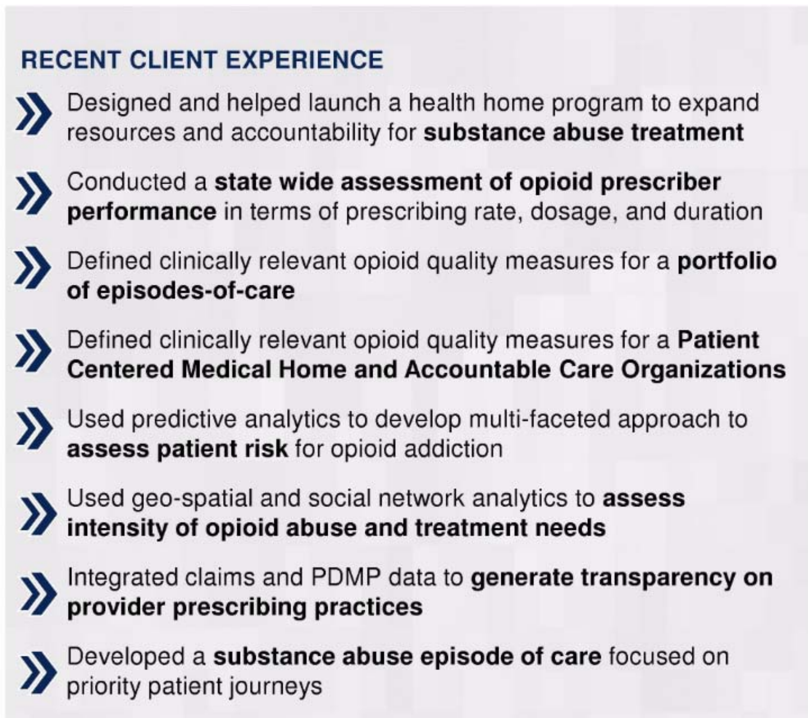


451. In other words, the "opioid prescribing rate" was a metric McKinsey worked with its client to boost for years. Now McKinsey measures the extent of the crisis by the same metric:



452. Meanwhile, McKinsey has partnered with Shatterproof, a national non-profit organization dedicated to reversing the addiction crisis in the United States, to report on overcoming stigma associated with opioid use disorder.[209] McKinsey touts the Shatterproof partnership on its webpage as an example of "our societal impact."[210]

453. In August 2017, McKinsey prepared a presentation entitled "Perspectives on Combatting the Opioid Crisis," which referenced its work on combatting opioid addiction for various other entities:



454. In June 2018, Dr. Charumilind and Mr. Latkovic, along with fellow McKinsey partner Elena Mendez-Escobar, published a public report, "Ten insights on the Opioid crisis from claims data analysis," stating information about the risks of opioids that McKinsey knew while advising Purdue to sell more opioids and higher dose opioids, and target the highest volume prescribers:

a. "Providers frequently prescribe opioids to patients with known or potential risk factors for abuse[;]"

[209] *See* https://www.shatterproof.org/sites/default/files/2020-07/A-Movement-to-End-Addiction-Stigma.pdf.
[210] *See* https://www.mckinsey.com/us/our-societal-impact.

b. "Approximately 35% of the patients given opioid prescriptions in our analysis had features that put them at increased risk for opioid abuse[;]"

c. "Most opioids are prescribed by providers other than the natural 'quarterback' of a patient's underlying complaint or condition. . . . This finding makes clear that high-dose prescribers and multi-prescriber patterns are separate issues—and both are important to address[;]" and

d. "A small portion of opioid use originates in emergency departments."[211]

455. Two months later, the same authors, joined by Ms. Lewis, published "Why we need bolder action to combat the opioid epidemic."[212] "Our research suggests that much broader – and bolder – action is required," they announced.[213]

X. TOLLING OF STATUTES OF LIMITATIONS

456. McKinsey is equitably estopped from relying upon a statute of limitations defense. Alongside its clients, McKinsey undertook active efforts to deceive the Plaintiffs and to purposefully conceal its unlawful conduct and fraudulently assure the public, including Plaintiffs, that opioids were non-addictive, effective, and safe for the treatment of long-term chronic pain and non-acute, non-cancer pain with the goal of increased sales, greater availability and access to opioids, and maximizing profits.

457. McKinsey and its clients were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing of opioids. This deceptive marketing—which included the above falsehoods that opioids were safer, less subject to abuse, and less addictive than other pain medications—was a substantial factor in the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

458. McKinsey deliberately advised its clients on marketing strategies and tactics to bolster their opioid products as non-addictive, safe, and efficacious without reliable scientific evidence to support same. McKinsey's consulting services were given confidentially, and both

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[211] https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/ten-insights-on-the-us-opioid-crisis-from-claims-data-analysis.

[212] *See* https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic.

[213] *Id.*

McKinsey and its clients concealed the content of those services from the public. In doing so, McKinsey concealed its role in shaping, editing, and providing the content of the false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers, and the public at large, including Plaintiffs.

459. McKinsey also concealed from Plaintiffs the existence of the Plaintiffs' claims by hiding it and its client's lack of cooperation with law enforcement. For example, in May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction and entered into a Corporate Integrity Agreement explained above. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

460. Nevertheless, even after the guilty pleas, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. Purdue also assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period. McKinsey participated extensively in these actions and provided Purdue with strategies and assistance to maximize sales as described in this Complaint. McKinsey knew that the actions it took with Purdue were unlawful, and yet deliberately proceeded in order to increase Purdue's sales and profits, and in turn to serve McKinsey's financial interests.

461. McKinsey affirmatively sought to convince the public that its clients' legal duties to report suspicious sales of opioids had been satisfied through public assurances that they were

working to curb the opioid epidemic. For example, after the 2007 Purdue guilty plea described above, McKinsey provided services to protect the company's public image and sales, aiding in the concealment of the addictive nature and dangers associated with opioid use and denying blame for the epidemic, attributing it instead solely to abuse and inappropriate prescribing. At the guidance and advice of McKinsey, Purdue and other McKinsey clients publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways, insisting they were good corporate citizens. Instead, McKinsey assisted Purdue, for example, with marketing campaigns and messaging that continued business as usual, indiscriminately targeting high prescribers and promoting opioids as safe but avoiding the pitfalls of the Corporate Integrity Agreement. These repeated misrepresentations misled regulators, prescribers, and the public, including the Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put the Plaintiffs on notice of potential claims.

462. Plaintiffs did not discover the nature, scope, and magnitude of McKinsey's misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

463. Prior to the applicable limitations period, Plaintiffs did not suspect, and had no reason to suspect, that McKinsey's conduct caused their injuries, including the consumption of Plaintiffs' resources as the opioid epidemic remains unabated.

464. McKinsey intended that its actions and omissions made with its clients would be relied upon, including by the Plaintiffs. The Plaintiffs did not know and did not have the means to know the truth due to McKinsey and its clients' actions and omissions.

465. The Plaintiffs reasonably relied on the affirmative statements developed by McKinsey and made by its clients regarding their purported compliance with their obligations under the law and consent orders, which were false and only intended to save the clients' public image.

466. McKinsey's fraudulent concealment has tolled the running of any statute of limitations. Through it and its clients' affirmative misrepresentations and omissions, McKinsey

actively concealed from Plaintiffs the risks associated with opioids that led to the opioids crisis. The wrongdoing, misrepresentations, and omissions by McKinsey has not ceased because the public nuisance remains unabated.

XI. CLAIMS FOR RELIEF

A. Multiple States' Plaintiffs

1. Aiding and Abetting Client Manufacturers' Negligence Per Se and Related Doctrines (All Plaintiffs)

467. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

468. Purdue Pharma owed a duty under federal law and the laws of the states not to promote or sell controlled substances, including opioids, for non-medical purposes, including abuse and diversion. Infants who could be injured *in utero* by their biological mothers' ingestion of misused, abused, or diverted opioids are included within the class of persons that these laws are intended to protect. McKinsey encouraged and substantially assisted Purdue in the violation of this duty, knowing that the conduct it was encouraging and assisting constituted a violation of this duty. McKinsey is therefore jointly and severally liable for the resulting injury to Plaintiffs.

469. Endo owed a duty under federal law and the laws of the states not to promote or sell controlled substances, including opioids, for non-medical purposes, including abuse and diversion. Infants who could be injured *in utero* by their biological mothers' ingestion of misused, abused, or diverted opioids are included within the class of persons that these laws are intended to protect. McKinsey encouraged and substantially assisted Endo in the violation of this duty, knowing that the conduct it was encouraging and assisting constituted a violation of this duty. McKinsey is therefore jointly and severally liable for the resulting injury to Plaintiffs.

470. Janssen owed a duty under federal law and the laws of the states not to promote or sell controlled substances, including opioids, for non-medical purposes, including abuse and diversion. Infants who could be injured *in utero* by their biological mothers' ingestion of misused, abused, or diverted opioids are included within the class of persons that these laws are intended to protect. McKinsey encouraged and substantially assisted Purdue in the violation of

this duty, knowing that the conduct it was encouraging and assisting constituted a violation of this duty. McKinsey is therefore jointly and severally liable for the resulting injury to Plaintiffs.

471. McKinsey encouraged and assisted Purdue, Janssen, Endo, and other opioid manufacturers to concentrate their sales and promotion resources on the highest-volume prescribers, knowing that the added prescriptions from these sales and promotion efforts would be written predominantly, if not exclusively, for "patients" who intended to abuse the drugs or divert them to the illegal secondary market.

472. McKinsey encouraged and assisted Purdue, Janssen, Endo, and other opioid manufacturers to increase their sales and promotion efforts to prescribers serving "abuse-prone" demographics, such as (and specifically) young men in economically depressed communities, knowing that the added prescriptions from these sales and promotion efforts would be written predominantly, if not exclusively, for "patients" who intended to abuse the drugs or divert them to the illegal secondary market.

473. McKinsey encouraged and substantially assisted Purdue, Janssen, Endo, and other opioid manufacturers to increase sales pressure on prescribers whose number, quantity, and/or dose range of opioid prescriptions were decreasing to resume their former patterns of prescribing and even to increase prescriptions beyond those former patterns. McKinsey knew, when it gave that encouragement and assistance, that most or all of the prescriber decreases were in response to government and public pressure to curb the abuse and diversion of opioids, meaning that the prescribers themselves or others believed that the former prescriptions had gone to patients who were abusing or diverting the drugs to the illegal secondary market. McKinsey knew that increases in the number, quantity, and dose range of opioid prescriptions in response to the sales pressure it encouraged its clients to apply would go to patients who intended to abuse or divert the drugs to the illegal secondary market.

474. McKinsey encouraged and substantially assisted Purdue, Janssen, Endo, and other opioid manufacturers to increase pressure and to bring new (and uniquely McKinsey-esque) kinds of pressure and leverage to bear on regulators, distributors, and pharmacies who had implemented, whether formally or informally, successful measures designed to control the

quantity and/or dose range of opioids distributed or dispensed in an effort to respond to government and public pressure to curb the abuse and diversion of opioids. This means that the distributors and pharmacies themselves believed that most or all of the decrease in the quantity and dose of opioids that they were distributing or dispensing was due to a decrease in opioids ultimately being supplied abusers and diverters—and McKinsey agreed with their assessments. The pressure tactics that McKinsey encouraged and assisted included McKinsey offering and using its leverage as consultant to multiple manufacturers who combined to make up a large percentage of the total prescription drugs distributed and dispensed, controlled and not controlled, and included threatening distributors and dispensers with the prospect that all or most of McKinsey's clients would attempt to bypass them individually or form a cartel or coop to bypass them.

475. Upon information and belief, McKinsey encouraged and substantially assisted Noramco (Janssen's affiliate), the maker of the *active* ingredient of the clear majority of *all* opioids sold in the United States during all relevant times, to increase pressure and to bring new kinds of pressure and leverage to bear on regulators who had implemented or were threatening to implement or tighten measures designed to control the quantity and/or dose range of opioids distributed or dispensed.

476. Upon information and belief, McKinsey encouraged and substantially assisted Noramco to increase sales pressure on other opioids manufacturers at times (for example, in 2001) when McKinsey identified an opportunity for one or more of Noramco's customers, such as makers of generics and immediate-release opioids, to increase sales and profits as a result of regulatory pressure or law enforcement pressure to reduce abuse and diversion of an individual brand opioid, such as Purdue's OxyContin, or a class of opioids, such as extended release oxycodone tablets—but not all opioids.

477. Upon information and belief, McKinsey leveraged its total market knowledge from other client manufacturers and Noramco to identify opportunities to capture or recapture someone else's lost sales to abusers and diverters—where regulators or law enforcement were focused on abuse and diversion of one or several opioid brands or classes only—and also leveraged its

relationships with, and knowledge of the capacities and abilities of other opioid manufacturers, to coordinate an all-industry response that simply shifted abuse and diversion from one brand or class of opioids to other brands and classes of opioids. For example, in response to DEA pressure and focus on abuse and diversion of OxyContin and extended release opioids in 2001 and succeeding years, McKinsey coordinated—that is, encouraged and assisted its clients through individual communications, but moved them all in the same direction by giving them coordinated encouragement and assistance—an industry-wide response that simply shifted those prescribers to abusers and diverters (who could no longer obtain OxyContin or extended-release oxycodone tablets) over to prescribing immediate release oxycodone and (to a lesser extent) immediate release hydrocodone and other opioid products.

478. The evidence that McKinsey knew that the sales, promotion, and pressure tactics it encouraged its clients to adopt were illegal and aimed at increasing sales of opioids that end up in the hands of abusers and diverters mostly comes from McKinsey's awareness and analysis of dips, flatlines, and changes in individual brand and aggregate opioid sales trends over the entire duration of the opioid epidemic, from the mid-1990s to the present. McKinsey knew that these dips, flatlines, and changes in brand and aggregate sales always and everywhere occurred in response to some (usually easy to identify) external pressure or measure taken by someone (usually a government agency but sometimes the company itself, as when a company releases an abuse-deterrent formulation or "ADF") to curb or curtail opioid abuse and diversion. In other words, McKinsey figured out very early in the opioid epidemic that the *only* downward driver (what analysts sometimes refer to as a "headwind") on individual brand and aggregate opioids in the market was pressure to curtail abuse and diversion and measures taken in response to this pressure.

479. McKinsey also discovered early on that the corollary to the finding described in the last paragraph—that all dips and flatlines in opioid sales were due to pressure or measures taken to control abuse and diversion—was that the easiest and surest path to boost the sales of all opioids or any particular opioid was to target abuse-prone populations and prescribers who served patients that abused and diverted opioids.

480. McKinsey deployed the corollary described in the last paragraph openly in its client recommendations during the early stages of the opioid epidemic (e.g., with Janssen in 2002), when it still thought no one was watching it or paying attention to it, and then slightly more cagily—but only slightly—in the later stages of the opioid epidemic. Indeed, McKinsey's self-appointed role with its opioid clients was to encourage and assist the client to uncover and overcome any pockets of reluctance or hesitation anywhere within the company to boost sales through tactics that foster the abuse and diversion of opioids—whether those pockets were found at the executive, management, or sales force levels. That is it. That is what McKinsey offered its clients, whether that is what they wanted when they hired McKinsey (as in the case of the Sacklers) or not (as in the case of Purdue's management team). An illustration of McKinsey employees' implicit understanding and faith in this self-appointed role comes from [redacted]

481. As a direct and proximate result of McKinsey's aiding and abetting of its clients' negligent and negligent *per se* conduct, the Minor Plaintiffs' biological mothers became dependent upon OxyContin and other opioids—in most cases the opioids were first prescribed by a licensed prescriber, but in some cases the opioids were subsequently obtained, including during pregnancy, through the illegal secondary market. Following birth, a direct and proximate result of McKinsey's aiding and abetting of its clients' negligent and negligent *per se* conduct, the Minor Plaintiffs suffered from, and continue to suffer from, developmental and congenital injuries from in utero opioid exposure, as described herein.

482. The conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an

amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

483. Plaintiffs' injuries as set forth herein were the foreseeable result of McKinsey's conduct.

484. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events had McKinsey's clients not breached their legal duties to exercise reasonable care, including by obeying laws intended to prevent harms such as the harms to the infant Plaintiffs from their mothers' opioid abuse and diversion, with McKinsey's knowing encouragement and substantial assistance.

2. Civil Conspiracy with Client Manufacturers to Commit the Torts of Negligence Per Se and Related Doctrines (All Plaintiffs)

485. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

486. Plaintiffs' description of the underlying duties of McKinsey's client-manufacturers is incorporated from the previous claim (captioned: "Aiding and Abetting Client Manufacturers' Negligence and Negligence Per Se (All Plaintiffs)").

487. Plaintiffs' description of McKinsey's conduct, behavior, and communications during its engagements with its clients is incorporated from the previous claim (captioned: "Aiding and Abetting Client Manufacturers Negligence and Negligence Per Se (All Plaintiffs)").

488. McKinsey conspired with its clients to violate the duties owed by the clients to Plaintiffs. It is unnecessary for each member of the conspiracy to owe independent duties to the Plaintiff. *See Post v. Amerisource Bergen*, 2020 WL 6438349, at *7-8 (N.D.W. Va. November 2, 2020) ("It is not necessary for every member of a conspiracy to be aware of every action taken in furtherance of the conspiracy to find liability. *Doe-1* rejected the argument that demonstration of a duty owed to plaintiff by a conspiracy defendant is an essential element of a civil conspiracy

claim."); accord *Jane Doe-1 v. Corp. of the President of the Church of Jesus Christ of Latter-Day Saints*, 239 W. Va 428, 477 (2017) ("We have not said that each member of a conspiracy must independently owe a duty to the plaintiff."). *Boorman v. Nevada Cremation Society, Inc*., 772 F. Supp. 2d 1309, 1315 (2011) ("Nevada does not require that each conspirator owe an independent duty to the plaintiff to support a civil conspiracy claim. To the extent such a duty is owed, it suffices under Nevada law to allege that Defendants […] owed a duty to Plaintiffs not to conspire with those who do owe fiduciary duties to Plaintiffs to breach those duties.")

489. McKinsey is liable for its participation in a civil conspiracy because it entered into agreements with its co-conspirators, including Purdue, Endo, and Janssen, and other opioid manufacturers, to participate in the unlawful acts or lawful acts intended to increase prescriptions, sales, distribution, and dispensing of opioids to known abusers and diverters. After McKinsey sold (encouraged) the client on the unlawful course of conduct, in each case, the client and McKinsey entered into an agreement that McKinsey would help to implement it, either by remaining involved in the day-to-day implementation of the duty violating conduct, or in some instances, by entering into an agreement that McKinsey would use its special contacts—for instance with regulators, distributors, pharmacies, and other manufacturers—to further the criminal conspiracy. McKinsey's agreement with Purdue in 2013 that McKinsey would offer special assistance in the high-level pressure tactics brought to bear against obstinate distributors and pharmacies is a perfect illustration of the kinds of post-encouragement agreements that McKinsey frequently entered into with its clients to help them sell more drugs by violating their duties.

490. McKinsey's status as an advisor, or service provider, or professional, is irrelevant to a finding to civil conspiracy liability. Other professionals in similar circumstances are routinely held liable for engaging in concerted action with their clients. *See Logan v. Morgan Lewis & Bockius LLP*, 350 So.3d. 404, 411-12 (Fla. 2d DCA 2022); *see also Cordell Consultant, Inc. Money Purchase Plan & Tr. v. Abbott*, 561 F. App'x 882, 884-86 (11th Cir. 2014); *Reynolds v. Schrock*, 197 Or. App. 564, 107 P.3d 52, *rev allowed*, 339 Or. 475 (2005) (attorneys); *In re RuralMetro Corp. Stockholders Litigation*, 102 A.3d 205, 219-20 (Del. Ch. 2014) (financial

advisors); *Jones v. KPMG LLP*, Memorandum Opinion and Order Denying Motion to Dismiss, Cause No. 1:17-cv-319 (S.D. Miss. Oct. 16, 2018) (accountants); *N.J. Dept. of Treasury v. Quest Communications Int'l Inc. et. al.*, 904 A.2d 775 (Sup. Ct. N.J – App. Div. 2005); *In re Enron Securities Derivative And Erisa Litigation*, 235 F.Supp.2d 549 (S.D. Tx. 2002) (consultants).

491. Control is not an element of a civil conspiracy, and Plaintiffs need not show that McKinsey controlled its clients. Plaintiffs need only to show an agreement to engage in unlawful conduct, or lawful conduct by unlawful means, and resulting injury Plaintiffs.

492. McKinsey joined, ratified, and participated in the conspiracies, and therefore became liable for all acts of its co-conspirators, including those undertaken in furtherance of the conspiracy prior to McKinsey's time of joining. McKinsey took the conspiracy as it found it. *See de Vries v. Brumback*, 53 Cal. 2d. 643, 2 Cal. Rptr. 764, 349 P.2d 532 (1960); *Ally Bank v. Castle*, 2012 WL 3627631, *10 (N.D. Cal. 2012).

493. Additionally, McKinsey's role as a hub in the conspiracy was unlike any other. McKinsey was in the unique position of knowing what competitor manufacturers were each doing to grow the market for opioids, and, just as importantly, when and why each of them had suffered setbacks due to enforcement activities, presenting opportunities for a different McKinsey client and co-conspirator to capture the illegal sales of the other. From this catbird's seat, McKinsey advised multiple manufacturers to implement substantially similar sales and marketing programs for OxyContin, Opana, Duragesic, Nucynta, and other opioids.

494. The existence of a conspiracy among manufacturers and others to increase the size of the opioid market through illegal sales tactics aimed at increasing abuse and diversion of opioids has already survived summary judgment pleadings before Judge Polster in MDL 2804. Plaintiffs hereby allege that McKinsey was also a member of the very same conspiracy alleged by litigants in MDL 2804. *See In re Nat'l Prescription Opiate Litigation*, 2018 WL 6628898 at *11 (N.D. Oh. December 12, 2018) ("Plaintiffs adequately pled that Defendants shared a general conspiratorial objective of expanding the opioid market…"); *In re Nat'l Prescription Opiate Litigation*, 2019 WL 4178610, at *11 (N.D. Ohio Sept. 3, 2019) (denying motions for summary judgment on civil conspiracy grounds against manufacturers and distributors and pharmacies).

495. Among the implementing regulations to the Controlled Substances Act is the requirement that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance," including opioids, become a "registrant." *See* 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.11(a). CSA registrants, including opioid manufacturers and distributors, must maintain a system to (i) identify and report suspicious orders, including identification of orders of unusual size, or frequency, or orders deviating from its normal pattern as well as (ii) maintain effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

496. Despite its lawful duties, McKinsey and its co-conspirators engaged in a scheme with the shared, overarching purpose of materially expanding prescription opioid use by overcoming or overwhelming (through pressure tactics) their fears and concerns about distributing, dispensing, and prescribing opioids in patterns, quantities, and doses that clearly indicated that the opioids were being abused or diverted. Instead of reporting suspicious conduct, as required by law, McKinsey conspired with its clients to foster, encourage, and pressure distributors, pharmacies, and prescribers to distribute, dispense, and prescribe opioids for abuse and diversion.

497. The conspiracy devised, implemented, and conducted by McKinsey and its co-conspirators was a common course of conduct designed to ensure that the co-conspirators illegitimately and unlawfully increased their sales and profits by creating, fostering, sustaining, and growing the illegal secondary market for opioid abuse and diversion.

498. McKinsey and its co-conspirators were each willing participants in the conspiracy, had a common purpose and interest in the object of the conspiracy, and functioned within a structure designed to effectuate the conspiracy's purpose.

499. As a result of the concerted action between the Purdue, other opioid manufacturer clients, and McKinsey, Plaintiffs have suffered damages.

500. Purdue, other companies in the opioids supply chain, and McKinsey are jointly and severally liable for the results of their concerted efforts.

501. As a direct and proximate result of the conspiracy between McKinsey and its clients for its clients to engage in negligent and negligent *per se* conduct, the Minor Plaintiffs' biological mothers became dependent upon OxyContin and other opioids—in most cases the opioids were first prescribed by a licensed prescriber, but in some cases the opioids were subsequently obtained, including during pregnancy, through the illegal secondary market. Following birth, a direct and proximate result of McKinsey's aiding and abetting of its clients' negligent and negligent *per se* conduct, the Minor Plaintiffs suffered from, and continue to suffer from, developmental and congenital injuries from in utero opioid exposure, as described herein.

502. The conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

503. Plaintiffs' injuries as set forth herein were the foreseeable result of the conduct of McKinsey and its con-conspirators.

504. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events had McKinsey's clients not conspired with McKinsey to breach their legal duties to exercise reasonable care, including by obeying laws intended to prevent harms such as the harms to the infant Plaintiffs from their mothers' opioid abuse and diversion, with McKinsey's knowing encouragement and substantial assistance.

3. Aiding and Abetting Client Manufacturers' Commission of the Tort of Public Nuisance (All Plaintiffs)

505. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

506. Plaintiffs' description of McKinsey's conduct, behavior, and communications during its engagements with its clients is incorporated from the previous claim captioned: "Aiding and Abetting Client Manufacturers Negligence and Negligence Per Se (All Plaintiffs)."

507. Section 821B of the Restatement (Second) Torts defines a "public nuisance" as "an unreasonable interference with a right common to the general public."

508. Manufacturers have a duty not to unreasonably interfere with the right of the general public to use and enjoy public spaces and to be free from the deleterious health effects of opioids in those spaces. Creating a condition that results in fear for safety, health, or well-being when using public spaces constitutes a public nuisance—when those conditions result from a breach of another legal duty, and especially when those breached duties have been codified in statutes or regulations. The breach of another legal duty in the process of significantly interfering with a public right is one of the factors—in most instances, the critical factor—in determining whether the significant interference was "unreasonable." Because McKinsey knowingly encouraged and substantially assisted its clients in the breach of those duties, McKinsey is also liable.

509. By knowingly promoting and selling drugs to prescribers whose patients were known abusers and diverters, and by pressuring others (such as distributors and pharmacists) to relax or eliminate measures taken by them to control abuse and diversion, in violation of federal and state laws, McKinsey's clients knowingly created, fostered, sustained, and grew the illegal secondary market for opioids. Because McKinsey knowingly encouraged and substantially assisted its clients in the breach of those duties, McKinsey is also liable for the public nuisance.

510. The creation and growth of the illegal secondary market for opioids caused not only increases in the risks and dangers associated with opioid addiction, but also interfered with the public right to the use and enjoyment of public spaces through the resulting, predictable increases in physical danger, likelihood of harassment, exposure to criminal activity, risk of theft of property, fear, filth, disease, and blight in public spaces that predictably result from a robust illegal secondary market for opioids.

511. The resulting epidemic required substantial expenditures of public funds, including expenditures for law enforcement and first responders.

512. Thus, by promoting and selling their controlled substances to prescribers whose patients were known abusers and diverters, and by pressuring others (such as distributors and pharmacists) to relax or eliminate measures taken by them to control abuse and diversion, in violation of federal and state laws, McKinsey's clients breached their duty to the public and to those, such as Plaintiffs, who suffered special harm from the significant and unreasonable interference with public rights, including the right to be free from the deleterious effects of an illegal secondary market for opioids and to the use and enjoyment of public spaces. In short, McKinsey's clients, with McKinsey's encouragement and substantial assistance, committed the tort commonly known as "public nuisance."

513. McKinsey's and its clients' conduct in creating, fostering, sustaining, and growing the illegal secondary market for opioid abuse and diversion does not only include what may be called the "supply-side" conduct described so far in this claim and the two previous claims—the illegal promotion and sale (and pressure on others to allow the illegal promotion and sale) of opioids. It also includes conduct of McKinsey described more fully in the claims below for encouraging, assisting, and conspiring with its client manufacturers in their failures to warn, concealment and suppression of adverse events and research findings, and their misrepresentations about the risks and benefits of their opioid products.[214] These actions and misrepresentations created and contributed to the "demand-side" conditions necessary for the public nuisance. Millions of individuals who took opioids for what they and their prescribers legitimately believed were legitimate medical purposes ended up addicted to opioids as a result of McKinsey's clients' misrepresentations and omissions, thereby driving the demand for the illegal secondary market for opioids, which McKinsey then encouraged clients to meet on the supply

[214] See especially the claims below captioned "Aiding and Abetting Client Manufacturers' Failure to Warn (All Plaintiffs)," and "Aiding and Abetting Client Manufacturers' Misrepresentations Regarding the Risks and Benefits of Opioids (All Plaintiffs)," which, as with the rest of the instant Amended Complaint, above and below, are incorporated in this section.

side through sales and other forms of pressure on prescribers, regulators, distributors, and pharmacies.

514. McKinsey's clients' misrepresentations and omissions regarding opioids generally, and Purdue's misrepresentation and omissions regarding OxyContin specifically, added fuel to the opioid epidemic within the Plaintiffs' communities that constitutes the public nuisance.

515. The public nuisance—the creation, fostering, growth, and sustaining of an illegal secondary market for opioid abuse and diversion—annoys, injures, or endangers the comfort, repose, health, and/or safety of others.

516. McKinsey knew at all times that the encouragement and substantial assistance that it was providing to its clients required its clients to breach their duties, and that this breach of client duties was creating, fostering, growing, and sustaining an illegal secondary market for opioids, which significantly interfered with the rights of the public.

517. As a direct and proximate result of the wrongful conduct of McKinsey's clients—and of McKinsey in knowingly encouraging and substantially assisting its clients in the breach of their duties, as set forth herein—a public nuisance resulted in the form of a robust illegal secondary market for opioid abuse and diversion. Not only did this public nuisance significantly interfere with the rights of the public, as described above—to use and enjoy public spaces without fear, danger, harassment, theft, and without encountering filth, disease, and blight, and to be free from the deleterious health and safety effects of an illegal drug trade—it also caused special injuries, of a completely different kind and character to those of the public, to the infant Plaintiffs on this complaint.

518. As a direct and proximate result of the public nuisance described in this section, every single infant plaintiff suffered at least one permanent developmental or congenital injury from in utero poisoning by opioids. Every single infant Plaintiff included in the instant Amended Complaint suffered at least one of the following injuries as a result of in utero opioid poisoning: gastroschisis (essentially being born with the intestines outside the body) or other congenital malformations such as brain and heart deformities, clubbed foot, and cleft palate; attention deficit disorders; permanent cognitive impairments, learning disabilities or other developmental and

language delays; respiratory impairments; vision impairments; and spina bifida or other neural tube defects. These injuries do not occur in adults exposed to opioids, even adults who become addicted to opioids. These injuries are clearly different in kind from the injuries suffered by all or most members of the public who experience mostly annoyance, fear, harassment, and theft in public spaces and also encounter filth, disease, and blight in those public spaces.

519. Therefore, under *Rest. 2d Torts* § 821C, the infant Plaintiffs can "recover damages in an individual action for a public nuisance" because they have "suffered harm of a kind different from that suffered by other members of the public."

520. McKinsey's and its clients' actions undertaken with the encouragement and substantial assistance of McKinsey were, at the very least, a substantial factor in opioids becoming widely available for abuse and diversion both by prescription and on the illegal secondary market. Those actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain, including during pregnancy. Without those actions, opioid use, misuse, abuse, addiction, and diversion would not have become so widespread, and the opioid epidemic that now exists would have been averted. Without those actions, the infant babies would have been born without the injuries described above.

521. Plaintiffs seek to recover only their own damages in these individual actions from McKinsey.

522. Plaintiffs' injuries as set forth herein were the foreseeable result of McKinsey's and McKinsey's clients' concerted conduct.

523. As a direct result of McKinsey's and McKinsey's clients' concerted conduct, Plaintiffs have individually suffered general and compensatory damages including, but not limited to, past and future medical expenses, pain and suffering, and loss of the earning capacity.

4. Civil Conspiracy with Client Manufacturers to Commit the Tort of Public Nuisance (All Plaintiffs)

524. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

525. Plaintiffs' description of the underlying duty of McKinsey's client-manufacturers is incorporated from the previous claim.

526. Plaintiffs' description of McKinsey's conduct, behavior, and communications during its engagements with its clients is incorporated from the previous three claims.

527. Section 821B of the Restatement (Second) Torts defines a "public nuisance" as "an unreasonable interference with a right common to the general public."

528. Manufacturers have a duty not to unreasonably interfere with the right of the general public to use and enjoy public spaces and to be free from the deleterious health effects of opioids in those spaces. Creating a condition that results in fear for safety, health, or well-being when using public spaces constitutes a public nuisance—when those conditions result from a breach of another legal duty, and especially when those breached duties have been codified in statutes or regulations. The breach of another legal duty in the process of significantly interfering with a public right is one of the factors—in most instances, the critical factor—in determining whether the significant interference was "unreasonable." Because McKinsey conspired with its clients to breach those duties, McKinsey is also liable.

529. McKinsey's conspiracy with its clients to increase profits by creating, fostering, growing, and sustaining an illegal secondary market for opioid abuse and diversion was an intimate, if usually oral, part of McKinsey's agreement with its clients. In the case of Purdue in 2013, McKinsey actually took it one step further, and entered into an oral agreement with Sackler family shareholders and board members to present cooked analyses to Purdue executives so they would feel compelled to return to pushing addictive drugs on high-volume prescribers serving patients who abused and diverted them, rather than pursuing management's preferred strategy of diversifying and pitching opioids to scrupulous but lower-volume prescribers.

530. By knowingly promoting and selling drugs to prescribers whose patients were known abusers and diverters, and by pressuring others (such as distributors and pharmacists) to relax or eliminate measures taken by them to control abuse and diversion, in violation of federal and state laws, McKinsey's clients knowingly created, fostered, sustained, and grew the illegal

secondary market for opioids. Because McKinsey conspired with its clients in the breach of those duties, McKinsey is also liable for the public nuisance.

531. The creation and growth of the illegal secondary market for opioids caused not only increases in the risks and dangers associated with opioid addiction, but also interfered with the public right to the use and enjoyment of public spaces through the resulting, predictable increases in physical danger, likelihood of harassment, risk of theft, fear, filth, disease, and blight in public spaces that predictably result from a robust illegal secondary market for opioids.

532. Thus, by promoting and selling their controlled substances to prescribers whose patients were known abusers and diverters, and by pressuring others (such as distributors and pharmacists) to relax or eliminate measures taken by them to control abuse and diversion, in violation of federal and state laws, McKinsey's clients breached their duty to the public and to those, such as Plaintiffs, who suffered special harm from the significant and unreasonable interference with public rights, including the right to be free from the deleterious effects of an illegal secondary market for opioids and to the use and enjoyment of public spaces. In short, McKinsey conspired with its clients to commit the tort commonly known as "public nuisance."

533. McKinsey's and its clients' conduct in creating, fostering, sustaining, and growing the illegal secondary market for opioid abuse and diversion does not only include what may be called the "supply-side" conduct described so far in this claim and the two previous claims—the illegal promotion and sale (and pressure on others to allow the illegal promotion and sale) of opioids. It also includes conduct of McKinsey described more fully in the claims below for encouraging, assisting, and conspiring with its client manufacturers in their failures to warn, concealment and suppression of adverse events and research findings, and their misrepresentations about the risks and benefits of their opioid products. These actions and misrepresentations created and contributed to the "demand-side" conditions necessary for the public nuisance. Millions of individuals who took opioids for what they and their prescribers legitimately believed were legitimate medical purposes ended up addicted to opioids as a result of McKinsey's clients' misrepresentations and omissions, thereby driving the demand for the illegal secondary market for opioids, which McKinsey then encouraged clients to meet on the supply

side through sales and other forms of pressure on prescribers, regulators, distributors, and pharmacies.

534. McKinsey's clients' misrepresentations and omissions regarding opioids generally, and Purdue's misrepresentation and omissions regarding OxyContin specifically, added fuel to the opioid epidemic within the Plaintiffs' communities that constitutes the public nuisance.

535. The public nuisance—the creation, fostering, growth, and sustaining of an illegal secondary market for opioid abuse and diversion—annoys, injures, or endangers the comfort, repose, health, and/or safety of others.

536. McKinsey knew at all times that the encouragement and substantial assistance that it was providing to its clients and the conspiracy with its clients that it was part of required its clients to breach their duties, and that this breach of client duties was creating, fostering, growing, and sustaining an illegal secondary market for opioids, which significantly interfered with the rights of the public.

537. As a direct and proximate result of the wrongful conduct of McKinsey's clients—and of McKinsey in knowingly conspiring with them to breach their duties, as set forth herein—a public nuisance resulted in the form of a robust illegal secondary market for opioid abuse and diversion. Not only did this public nuisance significantly interfere with the rights of the public, as described above—to use and enjoy public spaces without fear, danger, harassment, theft, and without encountering filth, disease, and blight, and to be free from the deleterious health and safety effects of an illegal drug trade—it also caused special injuries, of a completely different kind and character to those of the public, to the infant Plaintiffs on this Amended Complaint.

538. As a direct and proximate result of the public nuisance described in this section, every single infant plaintiff suffered at least one permanent developmental or congenital injury from in utero poisoning by opioids. Every single infant Plaintiff included in the instant Amended Complaint suffered at least one of the following injuries as a result of in utero opioid poisoning: gastroschisis (essentially being born with the intestines outside the body) or other congenital malformations such as brain and heart deformities, clubbed foot, and cleft palate; attention deficit disorders; permanent cognitive impairments, learning disabilities or other developmental and

language delays; respiratory impairments; vision impairments; and spina bifida or other neural tube defects. These injuries do not occur in adults exposed to opioids, even adults who become addicted to opioids. These injuries are clearly different in kind from the injuries suffered by all or most members of the public who experience mostly annoyance, fear, harassment, and theft in public spaces and also encounter filth, disease, and blight in those public spaces.

539. Therefore, under *Rest. 2d Torts* § 821C, the infant Plaintiffs can "recover damages in an individual action for a public nuisance" because they have "suffered harm of a kind different from that suffered by other members of the public."

540. McKinsey's and its clients' actions undertaken as part of this conspiracy were, at the very least, a substantial factor in opioids becoming widely available for abuse and diversion both by prescription and on the illegal secondary market. Those actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain, including during pregnancy. Without those actions, opioid use, misuse, abuse, addiction, and diversion would not have become so widespread, and the opioid epidemic that now exists would have been averted. Without those actions, the infant babies would have been born without the injuries described above.

541. Plaintiffs seek to recover only their own damages in these individual actions from McKinsey.

542. Plaintiffs' injuries as set forth herein were the foreseeable result of McKinsey's and McKinsey's clients' concerted conduct.

543. As a direct result of McKinsey's and McKinsey's clients' concerted conduct, Plaintiffs have individually suffered general and compensatory damages including, but not limited to, past and future medical expenses, pain and suffering, and loss of the earning capacity.

5. <u>Aiding and Abetting Client Manufacturers in the Breach of Their Duties to Warn (Failure to Warn)</u> <u>(All Plaintiffs)</u>

544. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

545. Purdue Pharma owed a duty to Plaintiffs to provide accurate and complete warnings of the foreseeable risks of harm associated with the use of their products, under both strict liability and negligence theories of products liability. McKinsey knowingly encouraged and substantially assisted Purdue in the violation of this duty, and is jointly and severally liable for the resulting injury to Plaintiffs.

546. Endo owed a duty to Plaintiffs to provide accurate and complete warnings of the foreseeable risks of harm associated with the use of their products, under both strict liability and negligence theories of products liability. McKinsey knowingly encouraged and substantially assisted Endo in the violation of this duty, and is jointly and severally liable for the resulting injury to Plaintiffs.

547. Janssen owed a duty to Plaintiffs to provide accurate and complete warnings of the foreseeable risks of harm associated with the use of their products, under both strict liability and negligence theories of products liability. McKinsey knowingly encouraged and substantially assisted Janssen in the violation of this duty, and is jointly and severally liable for the resulting injury to Plaintiffs.

548. McKinsey, in the course of its business with Purdue and other opioid manufacturers, encouraged and substantially assisted those manufacturers in concealing and suppressing adverse events, adverse clinical trial data, and adverse findings in published data concerning the true risks of, knowing that what it was encouraging and assisting was the concealment of adverse information, which constituted a breach of its clients' duties.

549. One of the primary mechanisms by which McKinsey encouraged and substantially assisted its clients was in reviewing, editing, and even ghost-writing its communications with regulators, research summaries and abstracts, and even re-doing and overseeing its clients' data analyses. McKinsey also encouraged its clients to hire contract research organizations, and then McKinsey directed, supervised, and rode those contract organizations on the client's behalf. McKinsey did not just encourage and assist its clients in lying, concealing, and suppressing—it literally, in many cases, wrote the lie or the suppression language—knowing it was a lie or a misleading concealment of the truth and that its clients too often (from McKinsey's perspective)

lacked the courage to lie or suppress or conceal without being prodded and pushed to lie and conceal or had moral reservations about lying and concealing that had to be overcome—and then told the client to submit the lie or suppression language under the client's name.

550. While many of McKinsey's acts of suppression, concealment, and dishonesty on its clients' behalf predate these, a series of McKinsey lies—dutifully adopted by McKinsey clients—in the 2010s will illustrate the technique. In the 2010s, published literature of the harms to gestating babies, like Plaintiffs, from the use of opioids during pregnancy, reached a groundswell, to the point that they were getting the attention of the public and McKinsey's clients' regulators to ignore.

551. McKinsey instructed Purdue to attack the data as insufficient and inconclusive on the issue of congenital malformations and other birth defects and injuries associated with in utero opioid exposure. In 2013, and again in 2017, McKinsey ghostwrote such an attack for Purdue, which Purdue submitted to the FDA in a successful effort to keep the FDA from forcing Purdue and other opioid manufacturers to have to include a direct contraindication and black box warning against the use of opioids by pregnant women. Years later, in a presentation given to a large health insurer, McKinsey admitted that it knew the same published data was sufficient to show that opioid use in pregnancy caused fetal birth defects and congenital malformations, such as gastroschisis, and other developmental injuries suffered by Plaintiffs.

552. McKinsey knew that what it was encouraging and ghostwriting—the suppression of truthful information and the concealment from physicians and end users of necessary warnings concerning the safety of its clients' product—constituted a breach of its clients' legal duties.

553. The suppression and concealment of truthful information about the risks to gestating babies from maternal opioid use are significant and material factors in the decision of Plaintiffs' biological mothers to use or abuse opioids—whether they obtained their opioids during pregnancy through prescription or on the black market.

554. As a direct and proximate result of McKinsey's encouragement and participation in its clients' concealments and suppressions and lies and misrepresentations about the harms of opioids to gestating babies, the Minor Plaintiffs' biological mothers were prescribed or otherwise

obtained and ingested opioids during pregnancy when they would not have done so had they known the true risks and dangers of consuming opioids in pregnancy.

555. McKinsey also encouraged, assisted, and participated in its clients' concealments and suppression of the risks of opioid addiction.

556. As a direct and proximate result of McKinsey's encouragement and participation in its clients' concealments and suppressions and lies and misrepresentations about the true risks of opioid addiction from its clients' products, the Minor Plaintiffs' biological mothers were prescribed or otherwise obtained and ingested opioids and, in most instances for most Plaintiffs, became addicted to opioids prior to pregnancy. That pre-pregnancy addiction was, for most Plaintiffs' biological mothers, the other significant factor in their decision to consume opioids during pregnancy. These biological mothers would not have become addicted, and therefore would not have considered taking opioids in pregnancy, had they known the true risks and dangers of addiction to McKinsey's clients' opioids.

557. The conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

558. Plaintiffs' injuries as set forth herein were the foreseeable result of McKinsey's and McKinsey's clients' concerted conduct.

559. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events if McKinsey had not encouraged and assisted its clients in breaching their duties to warn.

6. Conspiring with Client Manufacturers in the Breach of Their Duties to Warn (Failure to Warn) (All Plaintiffs)

560. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

561. Purdue Pharma owed a duty to Plaintiffs to provide accurate and complete warnings of the foreseeable risks of harm associated with the use of their products, under both strict liability and negligence theories of products liability. McKinsey conspired with Purdue to violate this duty, and is jointly and severally liable for the resulting injury to Plaintiffs.

562. Endo owed a duty to Plaintiffs to provide accurate and complete warnings of the foreseeable risks of harm associated with the use of their products, under both strict liability and negligence theories of products liability. McKinsey conspired with Endo to violate this duty, and is jointly and severally liable for the resulting injury to Plaintiffs.

563. Janssen owed a duty to Plaintiffs to provide accurate and complete warnings of the foreseeable risks of harm associated with the use of their products, under both strict liability and negligence theories of products liability. McKinsey conspired with Janssen to violate this duty, and is jointly and severally liable for the resulting injury to Plaintiffs.

564. McKinsey, in the course of its business with Purdue and other opioid manufacturers, conspired with those manufacturers in concealing and suppressing adverse events, adverse clinical trial data, and adverse findings in published data concerning the true risks of, knowing that what it was encouraging and assisting was the concealment of adverse information, which constituted a breach of its clients' duties.

565. One of the primary mechanisms by which McKinsey conspired with its clients was in reviewing, editing, and even ghost-writing its communications with regulators, research summaries and abstracts, and even re-doing and overseeing its clients' data analyses, under an express or oral agreement with them.

566. While many of McKinsey's acts of suppression, concealment, and dishonesty on its clients' behalf predate these, a series of lies promulgated pursuant to these conspiracies in the 2010s will illustrate the technique. In the 2010s, published literature of the harms to gestating

babies, like Plaintiffs, from the use of opioids during pregnancy, reached a groundswell, to the point that they were getting the attention of the public and McKinsey's clients' regulators to ignore.

567. McKinsey conspired with Purdue to attack the data as insufficient and inconclusive on the issue of congenital malformations and other birth defects and injuries associated with in utero opioid exposure. In 2013, and again in 2017, McKinsey ghostwrote such an attack for Purdue, which Purdue submitted to the FDA in a successful effort to keep the FDA from forcing Purdue and other opioid manufacturers to have to include a direct contraindication and black box warning against the use of opioids by pregnant women. Years later, in a presentation given to a large health insurer, McKinsey admitted that it knew the same published data was sufficient to show that opioid use in pregnancy caused fetal birth defects and congenital malformations, such as gastroschisis, and other developmental injuries suffered by Plaintiffs.

568. McKinsey knew that the purpose of these conspiracies to ghost-write and oversee its clients' submissions to regulators and journals and others—the suppression of truthful information and the concealment from physicians and end users of necessary warnings concerning the safety of its clients' product—constituted a breach of its clients' legal duties.

569. The suppression and concealment of truthful information about the risks to gestating babies from maternal opioid use are significant and material factors in the decision of Plaintiffs' biological mothers to use or abuse opioids—whether they obtained their opioids during pregnancy through prescription or on the black market.

570. As a direct and proximate result of McKinsey's conspiracies with its clients to conceal, suppress, lie, and misrepresent the harms of opioids to gestating babies, the Minor Plaintiffs' biological mothers were prescribed or otherwise obtained and ingested opioids during pregnancy when they would not have done so had they known the true risks and dangers of consuming opioids in pregnancy.

571. McKinsey also conspired with its clients to conceal and suppress the risks of opioid addiction.

572. As a direct and proximate result of McKinsey's conspiracies with its clients to conceal, suppress, lie, and misrepresent the true risks of opioid addiction from its clients' products, the Minor Plaintiffs' biological mothers were prescribed or otherwise obtained and ingested opioids and, in most instances for most Plaintiffs, became addicted to opioids prior to pregnancy. That pre-pregnancy addiction was, for most Plaintiffs' biological mothers, the other significant factor in their decision to consume opioids during pregnancy. These biological mothers would not have become addicted, and therefore would not have considered taking opioids in pregnancy, had they known the true risks and dangers of addiction to McKinsey's clients' opioids.

573. The conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

574. Plaintiffs' injuries as set forth herein were the foreseeable result of McKinsey's and McKinsey's clients' concerted conduct.

575. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events if McKinsey had not conspired with its clients in breaching their duties to warn.

7. Aiding and Abetting Negligent Misrepresentation, Intentional Misrepresentation, Fraud (Actual and Constructive), and Deceit (All Plaintiffs)

576. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

577. Purdue Pharma owed a duty to Plaintiffs to exercise reasonable care when representing the risks and benefits of its products to the public and to prescribers, regulators,

physicians, and end-users. Purdue Pharma also had a duty not to knowingly misrepresent the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. McKinsey encouraged and assisted Purdue in the violation of these duties, and is jointly and severally liable for the resulting injury to Plaintiffs.

578. Endo owed a duty to Plaintiffs to exercise reasonable care when representing the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. Endo also had a duty not to knowingly misrepresent the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. McKinsey encouraged and assisted Endo in the violation of these duties, and is jointly and severally liable for the resulting injury to Plaintiffs.

579. Janssen owed a duty to Plaintiffs to exercise reasonable care when representing the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. Janssen also had a duty not to knowingly misrepresent the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. McKinsey encouraged and assisted Janssen in the violation of these duties, and is jointly and severally liable for the resulting injury to Plaintiffs.

580. McKinsey encouraged and assisted the following client misrepresentations of risks and benefits, among others:

a. Downplaying the substantial risks of addiction and other side effects of opioids generally, and Purdue's opioids specifically, including crafting Purdue's marketing plan to affirmatively state in sales calls and other marketing channels that Purdue's drugs were not as addictive or prone to abuse as they truly are; stating that classic signs of addiction were actually an indication of "pseudoaddiction" requiring administration of additional opioids, and omitting the high risks of addiction actually present;

b. Overstating the efficacy of opioids generally, and Purdue's opioids specifically, including making false statements regarding the effectiveness of the drugs for treating specific subsets of the patient population and their ability to improve patient function;

c. Misrepresenting the medical usefulness and necessity of opioids generally, and Purdue's opioids specifically, including affirmatively marketing these drugs for off-label uses without solicitation and not in response to questions from healthcare providers; and

d. Downplaying the substantial and known risks and dangers associated with opioid use during pregnancy, including misleading women of childbearing age thereby exposing countless children to opioids in utero.

581. McKinsey encouraged and assisted its clients to misrepresent and commit fraud by encouraging its clients to misrepresent and mislead the public, regulators, physicians, and end users about the benefits, as well as the risks, of its products. One of the techniques McKinsey encouraged its clients to adopt—which McKinsey itself then implemented—was to use knowingly faulty study designs and data analyses that were guaranteed to produce an outcome favorable to the client. In furtherance of this technique, McKinsey encouraged its clients to hire outside contract research organizations ("CRO") that could be trusted to follow McKinsey's supervision and instructions, and would in fact permit McKinsey to ghostwrite the study designs and analyses, in addition to summaries, discussions, and abstracts. McKinsey then rode the CROs and oversaw them to ensure that they produced the data and conclusions that McKinsey's clients needed to deceive the public, regulators, and physicians, so their clients could sell more opioids.

582. The example from Client Engagement No. D, *supra*, [redacted] illustrates the technique. [redacted]

[redacted]

583. McKinsey and its opioid clients' misrepresentations and omissions had a tendency to deceive others, violate public confidence, undermine doctor-patient trust, disrupt the mother/child dyad, and/or injure public interests.

584. McKinsey and its clients intended healthcare providers, including the Minor Plaintiffs' biological mother's healthcare providers, to rely upon it and its clients' false and misleading assertions regarding the risks, efficacy, benefits, and medical necessity of opioids to increase the number of opioid prescriptions made by healthcare providers.

585. Healthcare providers, including the Minor Plaintiffs' biological mothers' healthcare providers, did in fact rely on these false representations and omissions. As a result of their reliance, these healthcare providers prescribed opioids, often unnecessarily or in unnecessarily large quantities or high doses, to Minor Plaintiffs' biological mothers, including while they were of childbearing age or pregnant.

586. There is moral, ethical and legal blame attached to McKinsey as a result of the terrible injuries and suffering their misconduct caused, including the damage to Plaintiffs.

587. McKinsey acted with knowledge and willful intent, with reckless disregard for the rights of others, and/or intentionally and with malice towards others including the Minor Plaintiffs and their biological mothers.

588. As a direct and proximate result of McKinsey's encouragement and participation in its clients' misrepresentations about the true risks and benefits of opioid addiction from its clients' products, the Minor Plaintiffs' biological mothers were prescribed or otherwise obtained and ingested opioids and, in most instances for most Plaintiffs, became addicted to opioids prior to pregnancy. That pre-pregnancy addiction was, for most Plaintiffs' biological mothers, the other significant factor in their decision to consume opioids during pregnancy (in addition to McKinsey's and its clients' failure to warn of harm to fetuses). These biological mothers would not have become addicted, and therefore would not have considered taking opioids in pregnancy,

had they known the true risks and dangers of addiction to McKinsey's clients' opioids, or the false and limited nature of many of the claimed benefits.

589. The conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

590. Plaintiffs' injuries as set forth herein were the foreseeable result of McKinsey's encouragement and assistance of its clients in breaching their duties to warn.

591. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events if McKinsey had not encouraged and assisted its clients in breaching their duties to warn.

8. <u>Aiding and Abetting Negligent Misrepresentation, Intentional Misrepresentation, Fraud (Actual and Constructive), and Deceit (All Plaintiffs)</u>

592. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

593. Purdue Pharma owed a duty to Plaintiffs to exercise reasonable care when representing the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. Purdue Pharma also had a duty not to knowingly misrepresent the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. McKinsey conspired with Purdue in the violation of these duties, and is jointly and severally liable for the resulting injury to Plaintiffs.

594. Endo owed a duty to Plaintiffs to exercise reasonable care when representing the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. Endo also had a duty not to knowingly misrepresent the risks and benefits of its products

to the public and to prescribers, regulators, physicians, and end-users. McKinsey conspired with Endo in the violation of these duties, and is jointly and severally liable for the resulting injury to Plaintiffs.

595. Janssen owed a duty to Plaintiffs to exercise reasonable care when representing the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. Janssen also had a duty not to knowingly misrepresent the risks and benefits of its products to the public and to prescribers, regulators, physicians, and end-users. McKinsey Conspired with Janssen in the violation of these duties, and is jointly and severally liable for the resulting injury to Plaintiffs.

596. McKinsey conspired with its clients to make the following misrepresentations of risks and benefits, among others:

a. Downplaying the substantial risks of addiction and other side effects of opioids generally, and Purdue's opioids specifically, including crafting Purdue's marketing plan to affirmatively state in sales calls and other marketing channels that Purdue's drugs were not as addictive or prone to abuse as they truly are; stating that classic signs of addiction were actually an indication of "pseudoaddiction" requiring administration of additional opioids, and omitting the high risks of addiction actually present;

b. Overstating the efficacy of opioids generally, and Purdue's opioids specifically, including making false statements regarding the effectiveness of the drugs for treating specific subsets of the patient population and their ability to improve patient function;

c. Misrepresenting the medical usefulness and necessity of opioids generally, and Purdue's opioids specifically, including affirmatively marketing these drugs for off-label uses without solicitation and not in response to questions from healthcare providers; and

d. Downplaying the substantial and known risks and dangers associated with opioid use during pregnancy, including misleading women of childbearing age thereby exposing countless children to opioids in utero.

597. McKinsey conspired with its clients to misrepresent and mislead the public, regulators, physicians, and end users about the benefits, as well as the risks, of its products. One

of the techniques McKinsey encouraged its clients to adopt—which McKinsey itself then implemented—was to use knowingly faulty study designs and data analyses that were guaranteed to produce an outcome favorable to the client. In furtherance of this technique, McKinsey conspired with its clients to enter into a three-way agreement (although McKinsey's role in it may not have been committed to writing) to hire outside contract research organizations ("CRO") that would be required to follow McKinsey's supervision and instructions, and would in fact have to allow McKinsey to ghostwrite the study designs and analyses, in addition to summaries, discussions, and abstracts. McKinsey then rode the CROs and oversaw them pursuant to the conspiracy to ensure that they produced the data and conclusions that McKinsey's clients needed to deceive the public, regulators, and physicians, so their clients could sell more opioids.

598. The example from Client Engagement No. D, *supra*, [redacted] illustrates the technique. [redacted].

599. McKinsey and its opioid clients' misrepresentations and omissions had a tendency to deceive others, violate public confidence, undermine doctor-patient trust, disrupt the mother/child dyad, and/or injure public interests.

600. McKinsey and its clients intended healthcare providers, including the Minor Plaintiffs' biological mother's healthcare providers, to rely upon it and its clients' false and misleading assertions regarding the risks, efficacy, benefits, and medical necessity of opioids to increase the number of opioid prescriptions made by healthcare providers.

601. Healthcare providers, including the Minor Plaintiffs' biological mothers' healthcare providers, did in fact rely on these false representations and omissions. As a result of their reliance, these healthcare providers prescribed opioids, often unnecessarily or in

unnecessarily large quantities or high doses, to Minor Plaintiffs' biological mothers, including while they were of childbearing age or pregnant.

602. There is moral, ethical and legal blame attached to McKinsey as a result of the terrible injuries and suffering their misconduct caused, including the damage to Plaintiffs.

603. McKinsey acted with knowledge and willful intent, with reckless disregard for the rights of others, and/or intentionally and with malice towards others including the Minor Plaintiffs and their biological mothers.

604. As a direct and proximate result of McKinsey's conspiracy with its clients to misrepresent the true risks and benefits of opioid addiction from its clients' products, the Minor Plaintiffs' biological mothers were prescribed or otherwise obtained and ingested opioids and, in most instances for most Plaintiffs, became addicted to opioids prior to pregnancy. That pre-pregnancy addiction was, for most Plaintiffs' biological mothers, the other significant factor in their decision to consume opioids during pregnancy (in addition to McKinsey's and its clients' failure to warn of harm to fetuses). These biological mothers would not have become addicted, and therefore would not have considered taking opioids in pregnancy, had they known the true risks and dangers of addiction to McKinsey's clients' opioids, or the false and limited nature of many of the claimed benefits.

605. The conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

606. Plaintiffs' injuries as set forth herein were the foreseeable result of the conduct of McKinsey and its co-conspirator clients' conduct in breaching their duties to warn.

607. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events if McKinsey had not conspired with its clients in breaching their duties to warn.

B. <u>California Plaintiffs (Statutory Nuisance (Cal. Civ. Code §§ 3479 et seq.)</u>

608. The California Plaintiffs are Melissa Barnwell on behalf of her natural minor children, E.G. and C.G., and Jacqueline Ramirez on behalf of her natural minor child, R.R. California Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

609. For the reasons set forth in the Common Law Nuisance cause of action, the California Plaintiffs have a cause action for the special damages they have suffered from the public and/or private nuisance created by McKinsey pursuant to Cal. Civil Code §§ 3479 *et seq*.

C. <u>West Virginia Plaintiffs (Medical Monitoring)</u>

610. The West Virginia Plaintiffs are Hayden Travis Blankenship, on behalf of his natural minor child, Z.D.B.B.; Lisa Renee Daniels on behalf of her legally adopted minor child, A.K.D.; Timothy Lambert, on behalf of his natural minor children, T.J.L and M.L.; Beverly and Andrew Riling, on behalf of their legally adopted minor child, A.R.; and Cynthia Woolwine, on behalf of her natural minor children, B.W. and E.G.W. West Virginia Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

611. Plaintiffs assert a claim for Medical Monitoring under West Virginia based on Minor Plaintiffs' exposure to opioids, a known toxic substance, at a concentration higher than expected for the general population.

612. Such exposure was proximately caused by the McKinsey's tortious activities as pled herein.

613. Plaintiffs' exposure was the foreseeable result of the conduct of McKinsey's tortious activities as pled herein.

614. Plaintiffs face a lifetime of latent, dread medical and emotional conditions resulting from in utero exposure to opioids including but not limited to: brain damage, heart valve malformations, muscular-skeletal developmental disorders, speech and language disorders,

cognitive developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders, increased risk of addiction, and other effects set forth in this Complaint.

615. Plaintiffs will benefit from medical monitoring for the aforementioned medical and emotional conditions because testing and continued monitoring will bring to light the onset of these medical and emotional conditions so that treatment and intervention may begin at the earliest point possible.

616. Plaintiffs will also benefit from a medical monitoring program featuring an epidemiological component that collects and analyzes medical monitoring results. Such a program will enable heretofore unrecognized latent, dread diseases that may be associated with in utero opioid exposure to be identified so that treating professionals may better care for Plaintiffs and so that medical professionals engaged in the research and development of new treatment will have access to a broader universe of data.

617. Plaintiffs will require ongoing care for the aforementioned conditions which are known to result from in utero exposure to opioids including but not limited to medical care, psychiatric care, psychological care, physical therapy, cognitive therapy, and speech therapy.

618. The harm visited upon minor Plaintiffs is irreparable.

619. Given the immense wealth of McKinsey, such injunctive and equitable relief presents no undue burden or irreparable damage to McKinsey.

XII. PRAYER FOR RELIEF

Plaintiffs seek all legal and equitable relief permitted by law, including:

1. Pain and suffering, past, present, and future;
2. Medical expenses, past, present, and future;
3. Loss of earning capacity;
4. Punitive and/or exemplary damages;
5. Pre- and post-judgment interest;
6. Injunctive/equitable relief; and
7. Attorneys' fees and costs.

XIII. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: August 24, 2023

Respectfully submitted,

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